FUNDING OF THE CHILDHOOD VACCINE PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON
SELECT REVENUE MEASURES

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDREDTH CONGRESS

FIRST SESSION

MARCH 5, 1987

Serial 100-18

Printed for the use of the Committee on Ways and Means

U.S. GOVERNMENT PRINTING OFFICE

73-717 WASHINGTON : 1988

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

H781-9

COMMITTEE ON WAYS AND MEANS

DAN ROSTENKOWSKI, Illinois, *Chairman*

SAM M. GIBBONS, Florida
J.J. PICKLE, Texas
CHARLES B. RANGEL, New York
FORTNEY H. (PETE) STARK, California
ANDY JACOBS, JR., Indiana
HAROLD FORD, Tennessee
ED JENKINS, Georgia
RICHARD A. GEPHARDT, Missouri
THOMAS J. DOWNEY, New York
FRANK J. GUARINI, New Jersey
MARTY RUSSO, Illinois
DON J. PEASE, Ohio
ROBERT T. MATSUI, California
BERYL ANTHONY, JR., Arkansas
RONNIE G. FLIPPO, Alabama
BYRON L. DORGAN, North Dakota
BARBARA B. KENNELLY, Connecticut
BRIAN J. DONNELLY, Massachusetts
WILLIAM J. COYNE, Pennsylvania
MICHAEL A. ANDREWS, Texas
SANDER M. LEVIN, Michigan
JIM MOODY, Wisconsin

JOHN J. DUNCAN, Tennessee
BILL ARCHER, Texas
GUY VANDER JAGT, Michigan
PHILIP M. CRANE, Illinois
BILL FRENZEL, Minnesota
DICK SCHULZE, Pennsylvania
BILL GRADISON, Ohio
WILLIAM M. THOMAS, California
RAYMOND J. McGRATH, New York
HAL DAUB, Nebraska
JUDD GREGG, New Hampshire
HANK BROWN, Colorado
ROD CHANDLER, Washington

JOSEPH K. DOWLEY, *Chief Counsel*
M. KENNETH BOWLER, *Deputy Chief of Staff*
ROBERT J. LEONARD, *Chief Tax Counsel*
A.L. SINGLETON, *Minority Chief of Staff*

SUBCOMMITTEE ON SELECT REVENUE MEASURES

CHARLES B. RANGEL, New York, *Chairman*

RONNIE G. FLIPPO, Alabama
BYRON L. DORGAN, North Dakota
BARBARA B. KENNELLY, Connecticut
MICHAEL A. ANDREWS, Texas
FORTNEY H. (PETE) STARK, California
WILLIAM J. COYNE, Pennsylvania

GUY VANDER JAGT, Michigan
RAYMOND J. McGRATH, New York
JUDD GREGG, New Hampshire
HANK BROWN, Colorado

CONTENTS

Page

Press release of Friday, February 6, 1987, announcing the hearing 2

WITNESSES

U.S. Department of the Treasury, Dennis E. Ross, Tax Legislative Counsel 15

American Academy of Pediatrics:
Louis Z. Cooper, M.D 33
John C. Butler III 38
American Cyanamid Co., Lederle Laboratories Division, Robert B. Johnson and Ronald J. Cracas 81
American Medical Association, M. Roy Schwarz, M.D., and Ross Rubin 107
Bell of Atri, Inc., J. Anthony Morris 114
Butler, John C., III, Putnam, Hayes & Bartlett, Inc., American Academy of Pediatrics, and Merck & Co., Inc 38
Chalfie, Deborah, Help Abolish Legal Tyranny 116
Children's Hospital National Medical Center, Andrew D. McBride, M.D 105
Connaught Laboratories, Inc., David J. Williams and Carl Greco 97
Cooper, Louis Z., M.D., St. Luke's/Roosevelt Hospital Center, and American Academy of Pediatrics 33
Cracas, Ronald J., Lederle Laboratories Division, American Cyanamid Co 81
Determined Parents To Stop Hurting Our Tots (DPT/SHOTS), Marge Grant 120
Dissatisfied Parents Together, Jeffrey H. Schwartz 60
Grant, Marge, Determined Parents To Stop Hurting Our Tots 120
Greco, Carl, Connaught Laboratories, Inc 97
Help Abolish Legal Tyranny, Deborah Chalfie 116
Johnson, Robert B., Lederle Laboratories Division, American Cyanamid Co 81
Lederle Laboratories Division, American Cyanamid Co., Robert B. Johnson and Ronald J. Cracas 81
MacMaster, Douglas, Merck Sharp & Dohme Division, Merck & Co., Inc 87
Matsui, Hon. Robert T., a Representative in Congress from the State of California 4
McBride, Andrew D., M.D., Children's Hospital National Medical Center, and National Association of Children's Hospitals and Related Institutions 105
Merck & Co., Inc.:
John C. Butler III 38
Douglas MacMaster, Merck Sharp & Dohme Division 87
Morris, J. Anthony, Bell of Atri, Inc 114
National Association of Children's Hospitals and Related Institutions, Andrew D. McBride, M.D 105
Putnam, Hayes & Bartlett, Inc., John C. Butler III 38
Rubin, Ross, American Medical Association 107
St. Luke's/Roosevelt Hospital Center, Louis Z. Cooper, M.D 33
Schwartz, Jeffrey H., Dissatisfied Parents Together 60
Schwarz, M. Roy, M.D., American Medical Association 107
Waxman, Hon. Henry A., a Representative in Congress from the State of California, and Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce 9
Williams, David J., Connaught Laboratories, Inc 97

FUNDING OF THE CHILDHOOD VACCINE PROGRAM

THURSDAY, MARCH 5, 1987

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON SELECT REVENUE MEASURES,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:40 a.m., in room 1100, Longworth House Office Building, Hon. Charles B. Rangel (chairman of the subcommittee) presiding.

[The press release announcing the hearing follows:]

FOR IMMEDIATE RELEASE
FRIDAY, FEBRUARY 6, 1987

PRESS RELEASE #1
SUBCOMMITTEE ON SELECT REVENUE MEASURES
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
1102 LONGWORTH BUILDING
WASHINGTON, D.C. 20515
TELEPHONE: (202) 225-3627

THE HONORABLE CHARLES B. RANGEL (D., N.Y.), CHAIRMAN, SUBCOMMITTEE ON SELECT REVENUE MEASURES, COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES, ANNOUNCES A HEARING ON FUNDING OF THE CHILDHOOD VACCINE PROGRAM

The Honorable Charles B. Rangel (D., N.Y.), Chairman, Subcommittee on Select Revenue Measures, Committee on Ways and Means, U.S. House of Representatives, announced today that the Subcommittee will hold a hearing on the issue of funding for the childhood vaccine injury program on Thursday, March 5, 1987, beginning at 9:30 a.m. in the main Committee hearing room, 1100 Longworth House Office Building.

In announcing the hearing, Chairman Rangel stated, "P.L. 99-660, contains provisions which establish a program to compensate individuals who suffer injuries related to the administration of a childhood vaccine. However, the effective date of the program is delayed until an appropriate funding mechanism can be determined. The Subcommittee will consider the issue of providing a funding mechanism for the childhood vaccine injury program including, but not limited to, whether the appropriate source of funding should be the establishment of a trust fund and related excise tax on designated childhood vaccines or the provision of a spending entitlement."

BACKGROUND

The "National Childhood Vaccine Injury Act of 1986" (P.L. 99-660) creates a new system for compensating individuals who have been injured by vaccines routinely administered to children. The system consists of two separate, but related, parts and concerns only the actions of those injured by specified childhood vaccines and the manufacturers of such vaccines.

The system amends the Public Health Service Act to establish a Federal "no-fault" compensation program. All individuals injured by a vaccine administered after the date of enactment of the legislation are required to go through the compensation program. Judgments and awards entered under the compensation program must be expressly rejected before other remedies may be required. As enacted, the program will not become effective until the Congress adopts a funding system.

DETAILS FOR SUBMISSION OF REQUESTS TO BE HEARD:

Individuals and organizations interested in presenting oral testimony before the Subcommittee must submit their requests to be heard by telephone to Harriett Lawler [(202) 225-3627] no later than Friday, February 27, 1987, to be followed by a formal written request to Joseph K. Dowley, Chief Counsel, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. The Subcommittee staff will notify by telephone those scheduled to appear as soon as possible after the filing deadline. Any questions concerning a scheduled appearance should be directed to the Subcommittee [(202) 225-9710].

It is urged that persons and organizations having a common position make every effort to designate one spokesperson to represent them in order for the Subcommittee to hear as many points of view as possible. Time for oral presentations will be strictly limited with the understanding that a more detailed statement may be included in the printed record of the hearing. (See formatting requirements enclosed.) This process will afford more time for members to question witnesses. In addition, witnesses may be grouped as panelists with strict time limitations for each panelist.

In order to assure the most productive use of the limited amount of time available to question hearing witnesses, all witnesses scheduled to appear before the Subcommittee are required to submit 100 copies of their prepared statements to the Subcommittee office, room 1111 Longworth House Office Building, at least 24 hours in advance of their scheduled appearance. Failure to comply with this requirement may result in the witness being denied the opportunity to testify in person.

WRITTEN STATEMENTS IN LIEU OF PERSONAL APPEARANCE:

Persons submitting written statements for the printed record of the hearing should submit at least six (6) copies by the close of business, Friday, March 20, 1986, to Joseph K. Dowley, Chief Counsel, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. If those filing written statements for the record of the printed hearing wish to have their statements distributed to the press and the interested public, they may provide 100 additional copies for this purpose to the Subcommittee office, room 1111 Longworth House Office Building, before the hearing begins.

SEE ENCLOSED FORMATTING REQUIREMENTS.

* * * * * * *

Chairman RANGEL. The Subommittee on Select Revenue Measures, Committee on Ways and Means, will come to order.

This hearing is being held today in order to assist this subcommittee in determining the appropriate funding source for the childhood vaccine program which was enacted last year. This program contains provisions which establish a program to compensate individuals who suffer injuries relating to the administration of childhood vaccine. However, the effective date of the program is delayed until an appropriate funding mechanism can be determined. The subcommittee today will consider the issue of providing a funding mechanism for the childhood vaccine injury program including, but not limited to, whether the appropriate source of funding should be the establishment of a trust fund and related excise tax on designated childhood vaccines or whether the provision of a spending entitlement.

We look forward to hearing the comments of our witnesses today on these issues. We will start off by listening to one of the more prominent members of the Committee on Ways and Means, our colleague, Robert Matsui.

STATEMENT OF HON. ROBERT T. MATSUI, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. MATSUI. Thank you very much, Mr. Chairman, and members of the subcommittee. I would like to commend the committee for calling this hearing today on the National Childhood Vaccination Injury Act of 1986 and particularly applaud the efforts of my colleague from California, Henry Waxman, the chairman of the Energy and Commerce Subcommittee on Health, for his tireless efforts in drafting this legislation.

The Committee on Ways and Means is faced with a unique opportunity today. We have an opportunity to devise a financing mechanism for this program that will virtually ensure the availability and affordability of vaccines for all American children.

The vaccine and immunization programs have worked miracles in this country. In 1952 there were 57,000 cases of polio; in 1985 there were only 4. In 1941 there were more than 2,200 deaths from measles in a single year; last year there were only 2.

Our Nation's efforts to immunize children against infectious disease have been very successful over the past 20 years. We have watched as mortality and morbidity rates have declined substantially. Yet in recent years our childhood immunization program has teetered on the edge of disaster.

This year 2 million fewer children are receiving immunization than in 1981. The number of vaccine producers has dwindled and the cost of vaccines has risen dramatically. Our social and organizational abilities lag far behind our scientific and technological capabilities and research for new and improved vaccines has been cut back. This combination of circumstances has threatened the viability of our Nation's best defense against preventable disease.

I believe that it is vitally important as a national health policy priority that we not allow this essential program to be rolled back. However, our progress is being threatened on three fronts:

First, the rise in vaccine prices since 1981 has been substantial. The price of one vaccine, DPT, was reported to have increased by 2,000 percent in only 2 years.

Second, there is a major problem with the availability of vaccines. The current problem relating to the supply of vaccines is due to a number of factors including the concentration of production in a small number of manufacturers, limited stockpiling and a lack of competitive participation in the relatively small market for vaccine products.

But the third and probably the most crucial factor that threatens our childhood immunization program is the product liability crisis in the area of vaccination.

Congressman Waxman's well-crafted legislation carefully balances the concerns of those parents whose children have suffered as a result of participation in the immunization program and those pharmaceutical manufacturers who, through no fault of their own, cannot guarantee that their products are 100 percent reaction free.

The vaccine injury compensation program provides payments to the families who suffer vaccine related injuries while at the same time insuring liability safeguards for manufacturers. Furthermore the legislation has imposed stringent recordkeeping requirements on vaccine manufacturers and vaccine administrators.

The committee has many issues to deal with in attempting to develop an appropriate financing method for this compensation program but it is important that we keep five objectives in mind as we go through that process. We must insure:

First, that injured children and their parents are fairly compensated with a minimum of delay.

Second, that the system we design will increase the willingness of the public to participate in the immunization program.

Third, that it will encourage manufacturers not only to continue providing existing vaccines but also to devote resources to the development of new and improved vaccines.

Fourth, that we provide an immediate solution to the liability and insurance crisis facing the manufacturers.

And finally and perhaps most importantly, that the system be fiscally responsible.

There are before us several alternatives for financing the compensation program. It could be financed from general revenues, special dedicated excise taxes or a combination of both. Whatever compensation program is selected, the committee should recognize two vitally important issues.

First, that the public policy objectives of the act are the foundation of our commitment to eradicate communicable diseases. The benefits to society of eliminating childhood diseases far outweigh the burdens of costs associated with this program.

Second, if in the future there is a need to alter the funding mechanism of the program we must insure that the existing claimants' expectations of compensation are not jeopardized.

I would like to further add that Mr. Waxman's funding source in 1986, in my opinion, is an adequate one. It is one that makes a lot of sense. It is very difficult to expect in the near future any appropriations for this kind of a program. Having a funding mechanism that is based upon the manufacturers paying part of the cost in a

trust fund makes further sense because they participate in helping to alleviate the costs of injury borne by those who ultimately utilize the product; that is the children. I will be happy to answer any questions that the chairman or any of the subcommittee members might have.

[The prepared statement follows:]

THE HONORABLE ROBERT T. MATSUI
TESTIMONY BEFORE THE SUBCOMMITTEE ON SELECT REVENUES
THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986
MARCH 5, 1987

Mr. Chairman, I want to commend the committee for calling this hearing today on The National Childhood Vaccine Injury Act of 1986 and particularly applaud the efforts of my colleague from California, Chairman Henry Waxman, for his dogged determination and tireless effort in crafting this legislation.

The Ways and Means Committee is faced with a unique opportunity today. We have the opportunity to devise a financing mechanism for the National Vaccine Injury Compensation Program -- a program that will virtually ensure the availability and affordability of vaccines.

Vaccine and immunization programs have worked miracles in this country. In 1952 there were 57,000 cases of paralytic polio; in 1985 there were 4. In 1941 there were more than 2,200 deaths from measles in a single year; last year there were 2. Our nation's efforts to immunize children against infectious disease have been very successful over the past 20 years. We have watched as mortality and morbidity rates have declined substantially.

Yet in recent years, our Childhood Immunization Program has teetered on the edge of disaster. This year, 2 million fewer children are receiving immunization than in 1981. The number of vaccine producers has dwindled. The cost of vaccines has risen dramatically. Our social and organizational abilities has lagged far behind our scientific and technological capabilities, and research for new and improved vaccines has been cut back. This combination of circumstances has threatened the viability of our nation's best defense against preventable disease.

I believe that it is vitally important as a national health policy priority that we not allow this essential program to be rolled back. However, our progress is being threatened on three fronts:

First, the rise in vaccine prices since 1980 has been substantial. The price of one vaccine, DPT, was reported to have increased by 2000% in only 2 years.

Second, there is a major problem with the availability of vaccines. The current problems relating to the supply of vaccines are due to a number of factors, including concentration of production in a small number of manufacturers; limited stockpiling; and a lack of competitive participation in the relatively small market for vaccine products.

But the third and probably most crucial factor that threatens our childhood immunization program is the product liability crisis in the area of vaccines.

The unavoidable fact is that vaccines that immunize millions inevitably harm a handful. It is a particular tragedy that these children suffer from an effort to protect them and the public from the catastrophic medical costs of an epidemic. But it is perhaps even more tragic that the traditional tort system has not served the innocent who suffer in these limited instances. Ironically, this controversy over vaccine injuries has contributed the most to the crisis we currently face in our immunization program.

Vaccines are unique---their use is mandated by every state in the union as a prerequisite for children to attend school. They are heavily regulated from conception to consumption, and they are inherently safe. We cannot afford to be without them, but neither can we afford to let injured children go unattended.

Congressman Waxman's well-crafted legislation carefully balances the concerns of those parents whose children have suffered as a result of participation in the immunization programs and those pharmaceutical manufacturers, who through no fault of their own, cannot guarantee that their products are 100% reaction free. The Vaccine Injury Compensation Program provides payments to families who suffer vaccine-related injuries while at the same time ensuring liability safeguards for manufacturers. Furthermore, the legislation has imposed stringent record-keeping requirements on vaccine manufacturers and vaccine administrators.

I believe that such standards provide important incentives for manufacturers to continue their efforts in research and development of safer vaccines while at the same time ensuring immediate and reliable relief for those innocent children that may be at risk.

The Committee has many issues to grapple with in attempting to develop an appropriate financing mechanism for this compensation program, but I think it is important that we keep keep five objectives in mind as we go through this process:

We must ensure:

o that injured children and their parents are fairly compensated with a minimum of delay;

o that the system we design will increase the willingness of the public to participate in the immunization programs;

o that it will encourage manufacturers not only to continue providing existing vaccines, but also to devote resources to the development of new and improved vaccines;

o that we provide an immediate solution to the liability and insurance crisis facing our manufacturers; and finally, and perhaps most importantly;

o that the system be fiscally responsible.

We have before us several alternatives for financing the compensation program. The program could be financed from general revenues, special dedicated excise taxes or a combination of both. Furthermore, we must take into consideration the impact our decision will have on the government fiscal planning capabilities, the direct price of the vaccines, and the "price" of injury. There are many unanswered questions that we must attempt to address and I hope that today's hearing will help shed some light on them. I think that perhaps the most serious problem we face in deciding the most appropriate funding mechanism is the lack of adequate data. I know that other witnesses this morning have conducted extensive research and studies in this area and trust that they will be able to provide us with an accurate data base, essential for determining the true costs of the program.

Mr. Chairman, I look forward to working with the members of the subcommittee to develop a compensation program that meets the objectives of this legislation. Whatever compensation program that is selected, the Committee should recognize two issues of vital importance. First, that the public policy objectives of the National Vaccine Injury Program are the foundation of our commitment to eradicate communicable diseases. The benefits to society of eliminating childhood diseases far outweigh the burdens of costs associated with this program. Secondly, if in the future there is a need to alter the funding mechanism of the program, we must ensure that existing claimants' expectations of compensation are not jeopardized.

We are faced with the unique opportunity of developing a better system. If we fail to meet the challenge we must live with the consequences: decreased coverage rates; increased disease rates; increased prices; possible vaccine shortfalls and and adverse worldwide affect.

The health and welfare of our nation's children rests with our willingness to address this crucial matter.

Chairman RANGEL. Thank you. I welcome your volunteering to work with us to try to decide what the committee should recommend to the full committee.

Mr. Coyne.

Mr. COYNE. I have no questions.

Chairman RANGEL. Mr. Andrews.

Mr. ANDREWS. I want to thank our colleague for the contributions he has made and for his leadership.

Mr. BROWN. No questions.

Chairman RANGEL. Our next witness is Mr. Waxman.

We thank you for the contribution you have made. We are seeking your testimony and feel free to join with us.

STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND CHAIRMAN, SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT OF THE COMMITTEE ON ENERGY AND COMMERCE

Mr. WAXMAN. Thank you very much, Mr. Chairman.

I am delighted to appear before this subcommittee today to discuss funding proposals for the National Vaccine Injury Compensation Program.

Before I begin my comments on this program, I would like to thank you and the members of subcommittee on select revenues for holding these hearings.

This is a busy committee. Your time is limited and your work is complex. But I believe there is no more pressing or difficult public health problems today than the question of compensation for vaccine related injuries. Its resolution holds the key to the continued success of the public health miracle we have created in this country through our childhood immunization programs. In holding these hearings so early in the 100th Congress the subcommittee has recognized the significance of our past public health success, the seriousness of the current problem and the importance of its quick determination. I want to thank you for your clear demonstration of interest and concern.

As my colleague, Mr. Matsui, has noted, childhood immunization programs have transformed public health in this country. The statistics are just very dramatic. In 1952 there were 57,000 cases of paralytic polio. Last year there were four. In 1941 there were over 2,200 deaths from measles in a single year. Last year there were only two.

Every State requires that children be immunized before they start school. With vaccines we have avoided thousands of deaths, hundreds of thousands of disabilities and millions of dollars in medical costs.

But these vaccines which we take for granted are not completely safe. Some children will have adverse side effects for a few days. Some will have severe reactions, even mental retardation, permanent disability or death. There will not be many such reactions—for polio vaccine, for example, it is literally a one in a million chance—but some children will be hurt.

The particular tragedy and the paradox of vaccine injuries is that these children really are hurt in the line of public duty. They

are required to receive vaccinations, not just for their own protection but also for the group immunity necessary to protect the population from disease and from the catastrophic medical costs of epidemics.

But unlike veterans who are injured in a war or workers who are hurt on the job, these children have no place to file their grievances or turn to for care if they are hurt. The schools and clinics and private pediatricians that administer the shots are not prepared to take care of lifetime injury.

Many of the families of these children have been turning to the courts for relief. They have brought suits for negligence, for failure to warn, design defects, breach of warranty or inadequate research.

Some of these families have won and they sometimes win millions of dollars. Many more have lost; but the litigation costs and the occasional million dollar award have made pharmaceutical firms nervous about the vaccine market. They say it is less profitable to prevent illness than to treat it. They say affordable insurance is hard to find. They say they make the best vaccine they know how and they still lose lawsuits. They say they will increase prices again, again and again and perhaps they will have to leave the market all together.

These are difficult arguments, but it is clear that the vaccine injury controversy has slowed progress in the development of preventive health care. It is clear that there have been shortages already resulting in rationing of vaccine. It is clear that a number of vaccine injured children are left to fend for themselves on Medicaid or disability or whatever else may be available.

Many of these arguments have been made about other liability fights, but vaccines are a unique product. They are required of all children. They are regulated before, during and after production. They are inherently unsafe. And we cannot afford to be without them. This is why I think this is an issue that can be distinguished from all other issues when it comes to liability questions.

During the last Congress, a broad spectrum of conservatives, liberals, consumer advocates and pharmaceutical lobbyists drafted a compromise bill to deal with these complex questions. The result, the National Childhood Vaccine Injury Compensation Act, was enacted at the end of the last Congress after years of study and debate. It passed the review of doctors and parents and manufacturers and lawyers. As you recall, however, the bill did not contain a mechanism to fund the compensation provisions of the act.

When it is funded, the act will establish a no fault compensation system to pay for the medical, rehabilitation, and education costs of those children who are injured. If the injury is particularly severe, the program would pay for lost earnings of the disabled child and the pain and suffering he or she endures. In turn, the act will also limit that child's ability to sue the manufacturer of the vaccine. If an injury is the result of a bad vaccine or one inadequately researched or warned of, then the courts could still make awards. But those children who are the innocent statistics of the necessary war on infectious disease will not be forced to play the courtroom game of chance to get their medical bills paid.

As originally drafted, the compensation fund was to be paid for by an excise tax on vaccines. The tax was to be set by how danger-

ous each type of vaccine is known to be. The final price of a shot would thus reflect its true costs to society and those children who avoid the dangers of whooping cough, for example, would help pay for those children who react to the whooping cough vaccine itself.

Whatever form of financing this committee arrives at, one criterion must be met. The funding mechanism for the compensation program must be reliable. We are, through this act, asking some families with injured children to waive there rights to sue forever. We cannot expect these people to give up fundamental rights if they cannot depend on the compensation payments. And if they do not give these rights, the national vaccine injury compensation program will not work as it is designed to do. The results of such a failure would be a continuation of the courtroom lottery for compensation and a genuine threat of vaccine shortages and disease epidemics.

The act was no one's first choice. The parents group wanted fewer restrictions on litigation and more children eligible for compensation. The manufacturers wanted more protections from tort action and less specificity about awards. The doctors wanted to close off malpractice suits. But almost everyone agrees the compensation act would be better than the current problems. No one wants to return to terrors of crippling and killing disease. This Congress this year must finish this ounce of preventive work. We cannot afford the pounds of cure.

I appreciate this chance to be with you and I welcome any questions I might be able to be answer, Mr. Chairman.

[The prepared statement follows:]

TESTIMONY
OF
CONGRESSMAN HENRY A. WAXMAN
CHAIRMAN, SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

Good morning, Mr. Chairman. I am delighted to appear before this Subcommittee today to discuss funding proposals for the National Vaccine Injury Compensation Program.

Before I begin my comments on the this program, I would like to take the opportunity to thank you and the Members of the Subcommittee on Select Revenue Measures for holding these hearings.

This is a busy Committee. Your time is limited and your work is complex. But there is today no more pressing or more difficult public health problem than the question of compensation for vaccine-related injuries. Its resolution holds the key to the continued success of the public health miracle we have created in this country through our childhood immunization programs. In holding these hearings so early in the 100th Congress, the Subcommittee has recognized the significance of our past public health success, the seriousness of the current problem, and the importance of its quick determination. Thank you, Mr. Chairman, for this clear demonstration of interest and concern. I know you are as committed as I am to putting our national vaccine injury compensation program into place. And these hearings are an important first step in making that happen.

Background and Need for Legislation

Childhood immunization programs have transformed public health in this country. In 1952, there were 57,000 cases of paralytic polio; last year there were four. In 1941, there were over 2,200 deaths from measles in a single year; last year there were only two.

Every State requires that children be immunized before they start school. With vaccines, we have avoided thousands of deaths, hundreds of thousands of disabilities, and millions of dollars in medical costs.

But these vaccines, which we take for granted now, are not completely safe. Some children will have adverse side effects for a few days. Some will have severe reactions, even mental retardation, permanent disability, or death. There will not be many such reactions (for polio vaccine, for example, it is literally a one-in-a-million chance), but some children will be hurt.

The particular tragedy and the paradox of vaccine injuries is that these children really are hurt in the line of public duty. They are required to receive vaccinations not just for their own protection but also for the group immunity necessary to protect the population from disease and from the catastrophic medical costs of epidemics.

But unlike veterans who are injured in war or workers injured on the job, these children have no place to file their grievances or turn for care if they are hurt. The schools and clinics and private pediatricians that administer the shots are not prepared to take care of lifetime injury.

Many of the families of these children have been turning to the courts for relief. They have brought suits for negligence, for failure to warn, for design defect, for breach of warranty, for inadequate research.

Some of these families have won and they sometimes win millions of dollars. Many more have lost.

But the litigation costs and the occasional million-dollar award have made pharmaceutical firms nervous about the vaccine market. They say that it is less profitable to prevent illness than to treat it. They say that affordable insurance is increasingly hard to find. They say that they make the best vaccine they know how and they still lose lawsuits. They say that they will increase prices again and again and perhaps leave the market altogether.

These are difficult arguments, but it is clear that the vaccine injury controversy has slowed progress in the development of preventive health care. It is clear that there have been shortages already, resulting in rationing of vaccine. And it is clear that a number of vaccine-injured children are left to fend for themselves on Medicaid or disability or whatever else may be available.

Many of these arguments have been made about other liability fights. But vaccines are a unique product. They are required of all children. They are regulated before, during, and after production. They are inherently unsafe. And we cannot afford to be without them.

National Childhood Vaccine Injury Program

During the 99th Congress, a broad spectrum of conservatives and liberals, consumer advocates and pharmaceutical lobbyists, crafted a compromise bill to deal with these complex issues. The result -- the National Childhood Vaccine Injury Compensation Act-- was enacted at the end of the last Congress after years of study and debate. It passed the review of doctors and parents and manufacturers and lawyers. As you recall, however, the bill did not contain a mechanism to fund the compensation provision of the Act.

When it is funded, the Act will establish a no-fault compensation system to pay for the medical, rehabilitation, and education costs of those children who are injured. If the injury is particularly severe, the program would pay for lost earnings of the disabled child and for the pain and suffering that he or she endures.

In turn, the Act also will limit that child's ability to sue the manufacturer of the vaccine. If an injury is the result of a bad vaccine or one inadequately researched or warned of, then the courts could still make awards. But those children who are the innocent statistics of the necessary war on infectious disease will not be forced to play the courtroom game of chance to get their medical bills paid.

Funding

As originally drafted, the compensation fund was to be paid for by an excise tax on vaccines. The tax was to be set by how dangerous each type of vaccine is known to be. The final price of a shot would thus reflect its true cost to society, and those children who avoid the dangers of whooping cough, for example, would help pay for those children who react to the whooping cough vaccine.

But whatever form of financing this Committee arrives at, one criterion must be met. The funding mechanism for the compensation program must be reliable. We are, through this Act, asking some families with injured children to waive their rights to sue forever. We cannot expect these people to give up such fundamental rights if they cannot depend on the compensation payments. And if they do not give these rights, the National Vaccine Injury Compensation Program will not work as it is designed to do. The results of such a failure would be a continuation of the courtroom lottery for compensation and a genuine threat of vaccine shortages and disease epidemics.

Conclusion

The Act was no one's first choice. The parents group wanted fewer restrictions on litigation and more children eligible for compensation. The manufacturers wanted more protections from tort action and less specificity about awards. The doctors wanted to close off malpractice suits.

But almost everyone agrees that the Compensation Act would be better than the current problems. No one wants to return to the terrors of epidemics of crippling and killing disease.

This year the Congress must finish this ounce of preventive work. We cannot afford the pounds of cure.

Chairman RANGEL. Again, we want to thank you.

Unlike me, some people oppose this legislation. Feel free to stay with us and help us as we try to respond.

Since you have spent more time with this than we have and in testimony you mentioned that whatever mechanism we provide that it has to be one that the victims can depend on being paid, the only question I have is, what mechanism could we possibly come up with that would jeopardize payment if the U.S. Government is responsible?

Mr. WAXMAN. What I had in mind as the unreliable source would be if we had to go to an appropriation each year. If we ask a family to give up the right to sue and each year that family is supposed to get payments for the treatment of a child under the compensation program, we couldn't be sure that 5 years down the road or even next year there will be sufficient compensation available if we require an appropriation each year.

Chairman RANGEL. Have we any historic record as to where any Congress has given a right to people for compensation with prerequisites that the Government has failed to provide funds?

Mr. WAXMAN. The Government is not going to be providing the funds. The idea is not to use general government funds, but to use funds raised from a tax on the vaccine itself. Those funds would be used to set up a trust fund. The trust fund would then be responsible for providing compensation to the individual as set out by the system.

Chairman RANGEL. Maybe I am not asking the right question, but staff is here and I think they understand. I am trying to find out—you seem to be restricting our alternatives because of the possibility of risk, and certainly if we decide that the program should be funded as the Congress has directed that we do, you appear to be limiting our options because you are saying if we go one way, which is the appropriations route, I assume that would also be called the entitlement route.

Mr. WAXMAN. An appropriation is not an entitlement.

Chairman RANGEL. If we go the appropriations route, you fear that the money may not be there when the payments are due?

Mr. WAXMAN. That would be the fear. This bill would encourage people to go through the compensation system and accept the award of that compensation system and forego going to court. But if a family is trying to decide whether to settle the matter through the compensation system or go to court, there may be an insecurity there they then have to say that their child has a permanent injury and has to rely on being compensated down the road, but Congress authorized the money but may not appropriate it. That is different from entitlement.

Chairman RANGEL. I understand that, but did anything come up in your hearings that would indicate that we would say that a citizen would be entitled to recovery and the appropriations not be there when they need it?

Mr. WAXMAN. I know of no such example.

Chairman RANGEL. The staff informs me if this committee and the Congress goes the excise tax rather than the trust fund route that we can depend on the veto. That would not change your opinion about going that route.

Mr. WAXMAN. There is always a threat of veto. You can't evaluate whether you try something based on that threat. There was a threat of veto of this bill but the President did sign it. In addition, there are ways of packaging proposals so that the President would find it unattractive to veto it. I can't believe that when you have a compensation system for children that are hurt from vaccines that when it came down to it, he would veto it.

Chairman RANGEL. The Chair will yield to any Member who wishes to inquire at this time. We all thank you and as I said earlier please feel free to join us.

The next witness is Dennis Ross, Legislative Tax Counsel, Department of the Treasury. While Mr. Ross is coming I would like to advise the witnesses that the majority Members have been asked to meet with the Speaker at 12 noon, and if we are unable to complete our business by that time, we will recess for an hour and resume our hearing.

STATEMENT OF DENNIS E. ROSS, TAX LEGISLATIVE COUNSEL, U.S. DEPARTMENT OF THE TREASURY

Mr. Ross. Thank you, Mr. Chairman and members of the subcommittee.

I am pleased to have this opportunity to discuss the Treasury Department's views regarding possible methods for financing the compensation program for vaccine related injuries established by the National Childhood Vaccine Injury Act.

Chairman RANGEL. Would you give me an opportunity to ask whether there is unanimous consent for your 12-page statement to be entered into the record which would give you the opportunity to highlight your testimony?

Mr. Ross. That is fine.

Chairman RANGEL. The Chair has a motion from Mr. Coyne and without objection the full statement is in the record.

Mr. Ross. I will try to highlight my testimony. I would like to discuss some of the background that led to the Vaccine Act, discuss its specific provisions as well as the funding mechanism that was contemplated, although not included in the act, in an earlier form of the legislation.

Finally, I will describe the administration's serious concerns regarding both the form of the compensation program included in the act and the possible methods that have been suggested for its financing.

Despite those serious concerns regarding the provisions of the Vaccine Act, I wish to make it clear that the administration supports the creation of a no-fault compensation program for persons injured by childhood vaccines.

Within the next few weeks, we expect to propose a program that will provide equitable no fault compensation to injured persons, and predictable and hence insurable liabilities for vaccine manufacturers. Although I am not prepared to discuss the details of this alternative proposal, I wish to emphasize our willingness to work with this committee and other interested parties toward the development of a fair and responsible compensation program for persons injured by childhood vaccines. Perhaps this country's greatest

public health achievement in the 20th century has been the virtual elimination of many once feared communicable childhood diseases. My prepared testimony details the accomplishments and dramatic reductions in the incidence of paralytic polio and other serious childhood diseases.

This dramatic improvement in public health has been achieved principally as the result of the development of effective vaccines providing immunization from these diseases and the adoption of effective vaccination programs for children.

All States today have laws requiring one or more of the following vaccinations: DTP for diphtheria, tetanus, and pertussis; the MMR vaccination for measles, mumps, and rubella; and the polio vaccination. Approximately 50 million of these vaccines are administered annually in the United States.

While universal vaccination programs have been tremendously successful in improving public health they have not been without cost. Approximately one-half of all children receiving the DTP vaccination experience some type of local and systemic reaction—9,000 children annually will experience more serious reactions, including high fever and convulsions, and approximately 50 to 75 children annually suffer some serious long term or permanent injury. Fortunately serious injuries from other childhood vaccines are a good deal more rare although they still occur too frequently.

The injuries caused to a few individuals as a result of participation in broadly beneficial mandatory vaccination programs raises an issue whether the injured individuals are to be compensated for their injury and if so who is to bear the cost of that compensation. This issue is by no means unique to childhood vaccines. It has become a matter of public debate in connection with injuries resulting from exposure to or use of goods and services ranging from asbestos to football helmets to a broad variety of medical care.

In general compensation for vaccination related injuries like most other product liability and medical malpractice injuries has been accomplished through the tort system, with those injured filing lawsuits against the persons allegedly responsible.

In recent years, however, there has been an increasing tendency of the courts to find the producers of goods and services responsible for injuries caused by their products. Moreover there has been a growth in the number of very large awards for noneconomic compensatory damages, pain and suffering, and for punitive damages. These developments have resulted in large losses to the providers of many goods and services as well as to their insurers. In this respect the experience of vaccine manufacturers is clearly illustrative. In 1985 100 lawsuits claiming damages for DTP vaccine related injuries were filed against Lederle Laboratories, exceeding the number of claims filed against Lederle in the 3 previous years combined. Merck Sharp & Dohme report a similar although less sharp rise in the number of claims filed against it for MMR vaccine-related injuries.

A recent judgment against American Cyanamid awarded $2 million in compensatory damages and $8 million in punitive damages for injuries resulting from polio vaccinations.

Although this award was subsequently reversed, it nevertheless had a chilling effect on vaccine manufacturers and their insurers.

Primarily as a result of increasing and unpredictable tort litigation and a related inability to obtain adequate insurance at an acceptable cost, several drug companies, including Wyeth Laboratories and Parke Davis, have recently ceased producing childhood vaccines. Their departure has left only three producers of the standard vaccines for the entire United States market. DTP is produced by Lederle and Connaught laboratories. The MMR vaccine is produced only by Merck. The oral polio vaccine is produced only by Lederle.

Producers of the DTP vaccine are exposed to the greatest tort liability risk. Because of its inability to obtain insurance, Connaught did not produce the DTP vaccine for a 9-month period between 1984 and 1985.

With that background, Mr. Chairman, let me turn to the specific provisions of the act. The act establishes the compensation program that is intended to serve as the primary source of compensation for injuries caused by DTP, MMR, and polio vaccinations. The act also modifies the tort law by limiting the remedies that may be sought from vaccine manufacturers. The act did not include however a funding mechanism for its compensation program, and neither that program nor the modification in the State tort law would go into effect until a funding mechanism is provided.

Under the act's compensation program, claims for compensation would be filed in the federal district court.

Each claim, however, would be assigned to a judicially appointed special master who would examine the claim and make a proposed finding on its merits and as to the amount of compensation. The finding would be subject to review by the district court.

In general, compensation would be awarded under the program for injuries that occurred within stated time periods after vaccination as well as for any other injury that a claimant could prove was caused by the vaccine. The compensation would not be awarded if the preponderance of the evidence indicated that the injury was not caused by administration of the vaccine. A successful claimant ordinarily would be entitled to receive reimbursement of medical, rehabilitative and special educational expenses, damages for lost earnings, damages for pain and suffering and emotional distress in an amount not to exceed $250,000 and death benefits also subject to a $250,000 cap. No punitive damages would be awarded under the program and the program would also pay reasonable attorneys fees for all successful claims as well as for unsuccessful claims that were nevertheless filed in good faith and had a reasonable basis. As I have indicated the act's compensation program is intended to provide the primary source of compensation for vaccination injury. Thus, injured persons would be barred from filing a state tort claim against a vaccine manufacturer unless compensation is first sought under the program.

An injured person would have the option however of rejecting any award under the compensation program and proceeding against the manufacturer through the tort system. In those cases the vaccine act would modify state tort laws in several respects. These modifications would make it more difficult, but perhaps only marginally so, for injured persons to recover punitive damages from manufacturers and it would also provide specific defenses for manufacturers against other damage claims.

Although the compensation program generally would apply only to injuries resulting from vaccines administered after the effective date of the act compensation would also be provided for certain claims relating to prior vaccinations. As I have indicated, the act did not include a funding mechanism but an earlier form of the legislation would have provided for a newly created national vaccine injury compensation trust fund to be funded principally by revenues generated by a manufacturers excise tax on each dose of vaccine. The excise tax would have been indexed for inflation and would have been based on estimates of the proportionate share of compensation costs attributable to the particular vaccines.

In signing the legislation that contained the Vaccine Act, President Reagan indicated his support for the goal of compensating persons who suffer injuries as a result of childhood vaccinations. The President, however, also expressed very serious reservations concerning the compensation program contained in the act and the financing program that was contemplated although not enacted.

The President's and the administration's concerns regarding the compensation program contained in the Vaccine Act are basically threefold.

First, the compensation program would not serve as the exclusive source of compensation for vaccination injuries but would merely represent an alternative and in many cases preliminary forum to the tort system. Despite the modifications to the tort system I have discussed above, it can be expected many injured persons with potentially large claims, particularly for pain and suffering, would still resort to the tort system. This would undermine the basic goal of the Vaccine Act to provide equitable compensation to injured persons while enabling manufacturers to produce beneficial vaccines without threat of financial ruin.

Second, the Vaccine Act's compensation program would entail unnecessarily high administrative costs. The payment of attorneys' fees of all successful and many unsuccessful claimants would encourage claims of questionable merit and seriousness. In addition, for the larger claims that would ultimately be pursued through tort litigation, the compensation program would simply represent an additional layer of administrative costs.

Finally, Mr. Chairman, we are concerned by the Vaccine Act's delegation to the judicial branch of responsibility for administering the compensation program. The judiciary is not well equipped to assume oversight responsibility for the program. In addition, we are concerned that the delegation of such responsibility would raise possible constitutional issues regarding the separation of powers.

Let me turn now to the question of funding the Vaccine Act. I should, however, note at the outset that many of the administration's specific concerns regarding possible methods for financing the compensation program reflect broader concerns regarding the basic form of that program as well as the assumption that the program should be financed with Federal tax revenues. As I have indicated, in several weeks the administration will propose an alternative no-fault compensation program that should permit vaccine manufacturers to obtain workable insurance arrangements. We believe this approach is consistent with the goal of providing equitable compensation but will result in a more efficient allocation of

costs and benefits. We thus strongly urge that the issue of funding the Vaccine Act not be taken up without a serious reexamination of the basic structure of the compensation program itself.

One of our general concerns with regard to funding the Vaccine Act is the program's possible precedential effect. As I indicated earlier, the problem of compensating injured persons and properly allocating the costs of such compensation is not limited to childhood vaccines but exists indeed for a wide range of goods and services; thus among our concerns with respect to any public funding mechanism for the Vaccine Act is that it could encourage the creation of similar Federal programs for other persons injured by other goods and services.

In addition, a public funding mechanism would supplant market pricing and private insurance as means for providing compensation and allocating the costs of such compensation to the appropriate producers.

This is neither necessary nor appropriate and would eliminate an important incentive for manufacturers to produce safer vaccines. Although the administration has general objections to any public funding mechanism for the Vaccine Act, funding the compensation program through an excise tax is perhaps the least attractive alternative. In the first place creation of a new excise tax and a related trust fund would entail substantial administrative costs. More importantly however we are more concerned that funding the Vaccine Act's compensation program through an excise tax would create a substantial risk. The program would either operate at a deficit or be unable to compensate many injured persons. Since excise tax rates could be adjusted by Congress, maintenance of an adequate funding level would depend on reasonably accurate predictions of the numbers and amounts of claims. For a variety of reasons, however, accurate predictions of future claims are not very likely.

First, the Vaccine Act's provisions relaxing standards of proof and reimbursing attorneys' fees, even for unsuccessful claimants, would encourage the filing of many claims that are not filed under the present system. Second, it is difficult to predict the number of cases in which claimants would resort to the tort system after initially proceeding under the vaccine compensation program.

Third, the Vaccine Act covers at least the first 3,500 active cases to file a claim. The actual number of back cases that exist and the amount they entail are simply not known. Without knowing the number of individuals who would receive compensation from the program or the amount of their compensation, it would of course be impossible to set appropriate excise tax rates.

The danger that the compensation program would be inadequately funded is compounded by the fact that the program would be operated on a pay as incurred basis. Under that approach no payment would be made to injured persons for long-term medical care and similar future costs until those costs were incurred. It would thus be difficult to recognize and correct any funding deficiencies before they became unmanageable in size.

Mr. Chairman, as you know, we have had some experience with compensation programs funded by a targeted excise tax. In particular, the black lung trust fund employs a structure similar to that

contemplated for the vaccine trust fund. The history of the black lung trust fund illustrates the tendency of compensation programs to expand in scope and cost and the difficulty of funding a compensation program with excise tax revenues when eventual outlays are unknowable. The black lung disability trust fund has been operating at deficits since its initial creation in 1977 and is now some $2.8 billion in debt.

The basic alternative to funding the Vaccine Act through an excise tax would be through appropriations from general revenues. The administration also opposes this form of funding; given the existing pressures on Government spending, any new program funded from general revenues would simply divert resources from existing activities.

Moreover, appropriations can generally be reduced or eliminated as part of the annual budget process. If the proper funding amount is not fixed or guaranteed on a long-term basis, injured persons may have little incentive to accept awards under the compensation program rather than pursuing their claims through the tort system. This would of course undermine the basic purpose of the compensation program.

In summary, Mr. Chairman, the administration has serious reservations about the compensation program envisioned in the Vaccine Act as well as any public funding mechanism that might be adopted to finance it. We continue to support the basic objective of the act and will work to produce a fair and responsible program for compensation of persons injured by childhood vaccines.

That concludes my remarks. I will be glad to respond to any of your questions.

[The prepared statement follows:]

For Release Upon Delivery
Expected at 9:30 a.m., EST
March 5, 1987

STATEMENT OF
DENNIS E. ROSS
TAX LEGISLATIVE COUNSEL
DEPARTMENT OF THE TREASURY
BEFORE THE
SELECT REVENUE MEASURES SUBCOMMITTEE
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

Mr. Chairman and Members of the Subcommittee:

I am pleased to have this opportunity to discuss the Treasury Department's views regarding possible methods for financing the compensation program for vaccine-related injuries established by the National Childhood Vaccine Injury Act of 1986, P.L. 99-660 (the "Vaccine Act").

I will begin by discussing the factors that led to the adoption of the Vaccine Act. I will then discuss the compensation program established by the Vaccine Act and the tax provisions that were considered in connection with, but not ultimately included in, the Vaccine Act. Finally, I will describe the Administration's serious concerns regarding both the form of the compensation program and possible methods that have been suggested for financing the program.

Despite the Administration's concerns regarding the provisions of the Vaccine Act, I wish to make it clear that the Administration supports creation of a no-fault compensation program for persons injured by childhood vaccines. Within the next few weeks, we expect to propose a program that will provide equitable, no-fault compensation to injured persons, and predictable (and hence insurable) liabilities for vaccine manufacturers. Although I am not prepared today to discuss the details of this alternative proposal, I wish to emphasize our willingness to work with this Committee and other interested parties in designing a fair and responsible compensation program for persons injured by childhood vaccines.

Background

Perhaps the greatest public health triumph of the United States in the twentieth century has been the virtual elimination of the threat of many once feared communicable childhood diseases. In 1952, more than 20,000 cases of paralytic polio were reported in the United States. By 1986, the number of reported cases had dropped to two. In the 1930s, as many as 250,000 cases of pertussis (whooping cough) were reported annually, resulting in annual deaths of up to 7,500. During the past ten years only 1,000 to 4,000 cases of pertussis have been reported annually, with deaths ranging from five to 20. Similar dramatic declines have been experienced in the incidence of diphtheria, tetanus, measles, mumps, and rubella.

This public health triumph has been achieved principally as a result of the development of effective vaccines providing immunization from these diseases and the adoption of effective vaccination programs for children. All states today have laws requiring one or more of the following vaccinations: diphtheria, tetanus, and pertussis (usually administered as a combination vaccine referred to as DTP), measles, mumps, and rubella (usually administered as a combination vaccine referred to as MMR), and polio.1/ Approximately fifty million doses of these vaccines are administered annually in the United States.

The success of mandatory vaccination programs is due in large part to the Federal government's efforts. Since 1962, through the Centers for Disease Control (CDC), the Department of Health and Human Services has provided direction and leadership to state and local health agencies in implementing these programs. The Federal government also provides substantial financial support for vaccination programs. CDC immunization grants to states currently pay for more than one-fourth of all childhood vaccines used in the United States. Moreover, the Federal government bears a share of the costs of childhood vaccines purchased under Medicaid's Early Periodic Screening, Diagnosis, and Treatment Program.

While universal vaccination programs have been tremendously successful, they have not been without cost. Approximately half of all children receiving the DTP vaccination experience some type of minor local or systemic reaction; up to 9,000 children annually experience more serious reactions, including high fevers, shock-like episodes, persistent or unusual crying, or convulsions.2/ Approximately 50 to 75 children suffer serious long-term or permanent injuries each year as a result of adverse reactions to the DTP vaccine, including prolonged convulsions and severe brain damage that can lead to mental retardation and even death.3/ Serious injuries from other childhood vaccines are more rare. The measles portion of the MMR vaccine is associated with serious central nervous system injuries approximately once per million doses of vaccine, while the polio vaccine is estimated to cause the recipient or the recipient's close nonimmune contacts to develop paralytic polio approximately once per 3 million doses.4/ The other childhood vaccines generally produce only minor side effects.

1/A series of three DTP vaccinations typically is given during the first year of life, with a fourth dose recommended in the second year of life and a booster dose prior to school entry. Two doses of oral polio vaccines typically are given during the first year of life, with a third dose in the second year and a fourth dose prior to school entry. A single MMR vaccination is given, typically at fifteen months of age.

2/Cody, "Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children," 68 PEDIATRICS No. 5, 650, 652 (November 1981). Hinman, "Pertussis and Pertussis Vaccine, Reanalysis of Benefits, Risks and Costs," 251 JAMA No. 23, 3109, 3111 (June 15, 1984).

3/Hinman, supra note 2, at 3111.
The Department of Health and Human Services is funding trials of new forms of pertussis vaccines in an effort to bring a safer pertussis vaccine to the United States market.

4/Immunization Practices Advisory Committee. Poliomyelitis Prevention. Morbidity and Mortality Weekly Report, v. 31, January 29, 1982.

Evaluation of the number of injuries caused by childhood vaccinations is difficult, since initial doses generally are administered during the first year of life -- a time when many disabilities first become evident. Thus, in many cases, the onset or manifestation of disabilities such as mental retardation, cerebral palsy, and epilepsy may be temporally related to a vaccination, although not actually caused by it.

The injuries caused to a few individuals as a result of participation in mandatory vaccination programs that are beneficial to most raises the important social policy issue of whether the injured individuals are to be compensated for their injuries and, if so, who is to bear the cost of compensation. This is by no means a unique issue; it has become a matter of public debate in connection with injuries resulting from exposure to or use of goods and services ranging from asbestos to football helmets to medical care.

In general, compensation for vaccination-related injuries, like most other product liability and medical malpractice injuries, has been accomplished through the tort system, with those injured filing lawsuits against the persons who are alleged to be responsible for causing the injuries. Although state tort laws differ, the producer of a product generally is liable for injuries caused by the product if it is shown that the injuries were caused by the product and the producer was negligent. In most states, negligence need not be shown if it can be shown that a defect existed in the design, manufacture, or instructions for use of the product. In recent years, there has been an increasing tendency of the courts to find the producers of goods and services responsible for injuries caused by those goods and services. Moreover, there has been a growth in the number of very large awards for noneconomic compensatory damages, such as pain and suffering, and for punitive damages. These developments have resulted in large losses for the providers of many goods and services and for their insurers, and have led many to call for major reforms to the tort system or for the development of alternative means to compensate injured persons.

The experience of vaccine manufacturers illustrates the broader tort and liability insurance "crisis." In 1985, 100 lawsuits claiming damages for DTP vaccine-related injuries were filed against Lederle Laboratories. This number exceeded the number of claims filed against Lederle in the three previous years combined. Merck Sharp & Dohme reports a similar, although less sharp, rise in the number of claims filed against it for MMR vaccine-related injuries. A recent judgment against American Cyanamid Co. awarded $2 million in compensatory damages and $8 million in punitive damages for injuries resulting from polio vaccination.5/ Although this award was subsequently reversed, vaccine manufacturers and their insurers anticipate increasing numbers of claims and awards of this magnitude.

Primarily as a result of increasing and unpredictable tort litigation and a related inability to obtain adequate insurance coverage at an acceptable cost, several drug companies, including Wyeth Laboratories and Parke, Davis & Co., have recently ceased producing childhood vaccines. Their departure has left only three producers of the standard childhood vaccines for the entire United States market. DTP vaccines are produced by Lederle Laboratories and Connaught Laboratories, the MMR vaccine is produced by Merck Sharp & Dohme, and the oral polio vaccine is produced by Lederle. Producers of the DTP vaccine are exposed to the greatest tort liability risk. Because of its inability to

5/Johnson v. American Cyanamid Co., District Court No. 81 C 2470 (Sedgwick County), rev'd 718 P. 2d 1318 (Kan. 1986).

obtain insurance, Connaught ceased producing DTP vaccine for a nine month period in 1984 and 1985. Currently, Connaught and Lederle set aside approximately $8 per DTP vaccine dose as a self-insurance reserve for tort claims. This reserve represents more than 70 percent of the price of the vaccine.

Description of the Vaccine Act

The Vaccine Act establishes a compensation program that is intended to serve as the primary source of compensation for injuries caused by DTP, MMR, and polio vaccinations.6/ In addition, the Vaccine Act modifies state tort laws by imposing several limitations on the remedies that may be sought for such injuries from manufacturers of the vaccines. The Vaccine Act did not, however, include a funding mechanism for its compensation program, and neither that program nor the modifications of state tort laws will go into effect until a funding mechanism is enacted.

Claims Procedure. Under the Vaccine Act's compensation program, claims for compensation would be filed in Federal district court (with a copy served on the Secretary of Health and Human Services). Each claim would be assigned to a judicially appointed special master, who would examine and make a proposed finding on the merits of the claim and the amount of compensation. The underlying facts of the claim and the proposed findings of the special master would be subject to review by the district court.

Basis of Compensation. In general, compensation would be awarded under the program for specified injuries (or significant aggravations of such injuries) that occur within stated time periods after vaccination, and for any other injuries that a claimant proves were caused by a covered vaccine. Compensation would not be awarded if a preponderance of the evidence indicates that the injury was caused by factors unrelated to the administration of the vaccine.

Amount of Compensation. If compensation is awarded under the program, the claimant ordinarily would be entitled to receive reimbursement of medical, rehabilitative, and special education expenses (with future expenses paid as incurred), damages for lost earnings, damages for pain and suffering and emotional distress in an amount not to exceed $250,000, and death benefits in the amount of $250,000. No punitive damages could be awarded under the program. Reasonable attorneys' fees of all successful claimants and all unsuccessful claimants who filed in good faith with a reasonable basis for their claims also would be paid under the program.

6/Several bills addressing the issue of childhood vaccine-related injuries were introduced in the 99th Congress. H.R. 4777, supported by the Administration, proposed to rely on the tort system, as modified by the bill, to provide compensation for such injuries. The bill would have limited tort awards for noneconomic damages to $100,000 and eliminated punitive damage awards for such injuries. H.R. 5546, H.R. 5184, H.R. 1780, S. 1744, and S. 827, none of which was supported by the Administration, proposed Federally-administered and funded compensation programs. H.R. 5546 and S. 1744, without their financing provisions, were enacted as the Vaccine Act.

Tort System as Alternative Remedy. The Vaccine Act's compensation program is intended to provide the primary source of compensation for vaccination injuries. Thus, injured persons would be barred from filing a state tort claim against a vaccine manufacturer for more than $1,000 unless compensation is first sought under the program. The program would not, however, be the exclusive source of compensation. Tort liabilities of persons other than vaccine manufacturers, e.g., physicians, hospitals, and clinics, would not be affected by the Vaccine Act. Moreover, the Vaccine Act would permit an injured person to file a tort claim against a vaccine manufacturer if a claim under the compensation program were first pursued and the injured person elected not to accept the judgment of the district court under the program. Thus, individuals could pursue a tort suit if they believed that they would obtain a larger recovery from the tort system than from the compensation program. A lack of certainty that the compensation program will have adequate funds to pay for future medical expenses, discussed below, also could encourage claimants to pursue tort claims.

Modifications to Tort System. In those cases where injured persons elect to seek damages from vaccine manufacturers through the tort system, the Vaccine Act would modify state tort laws in several respects. The most significant modifications would make it more difficult, although perhaps only marginally so, for injured persons to recover punitive damages from manufacturers and would provide specific defenses for manufacturers against other damage claims.7/

Compensation for Retroactive Claims. The compensation program generally would apply to injuries resulting from vaccines administered after the effective date of the Vaccine Act. Compensation also would be provided, however, for certain claims relating to prior vaccinations.8/

7/The Vaccine Act would preclude any punitive damage award if a manufacturer shows that it had complied, in all material respects, with applicable provisions of Federal regulatory statutes, unless the plaintiff shows that there had been fraud or wrongful or illegal actions relating to the safety and effectiveness of the vaccine on the part of the manufacturer. The Vaccine Act also would modify state tort laws to permit warnings of dangers associated with the use of a vaccine to be given to the doctor administering the vaccine, rather than directly to the family of the child being vaccinated, and to preclude tort liability for "unavoidable" side effects in the absence of a finding that the vaccine was not properly prepared or was not accompanied by proper warnings. A showing by the manufacturer that it had complied with all material Federal regulatory requirements would give rise to a rebuttable presumption that the vaccine was accompanied by proper warnings (but would not give rise to a presumption that the vaccine was not defective in design).

8/Section 2111(b)(1)(B) of the Vaccine Act provides that "no person may file a petition for a vaccine-related injury or death associated with a vaccine administered before the effective date of [the Vaccine Act] if compensation has been paid under [the Vaccine Act] for 3500 petitions for such injuries or deaths." Although we understand that the intent of this provision is to permit compensation for up to 3,500 claims relating to prior vaccinations, the literal terms of the provision permit consideration of all claims filed before compensation has been awarded for 3,500 claims. The number of back claims to receive compensation could therefore greatly exceed 3,500.

Funding Provisions

Trust Fund and Excise Tax. As noted earlier, the Vaccine Act did not include a funding mechanism for its compensation program. Under H.R. 5546, an earlier version of the Vaccine Act, the costs of the compensation program would have been borne by a newly-created National Vaccine Injury Compensation Trust Fund (the "Vaccine Trust Fund"). The assets of the Vaccine Trust Fund would have consisted of (a) revenues generated by a manufacturers' excise tax on each dose of vaccine, (b) amounts recovered by the Vaccine Trust Fund as a result of subrogated claims against manufacturers, and (c) appropriations from the General Fund, repayable with interest (an initial repayable appropriation of $40 million would have been provided by H.R. 5546). The excise tax rates would have been based on estimates of the proportionate share of compensation costs attributable to each particular vaccine. The proposed tax rates were $1.56 per dose for DTP vaccines, $1.52 per dose for MMR vaccines, and $0.10 per dose for live polio vaccines. For calendar years after 1987, the rates would have been indexed for inflation.

Limited Federal Liability. Under H.R. 5546, any claim filed against the Vaccine Trust Fund could have been paid only out of the assets of the Vaccine Trust Fund. If the Vaccine Trust Fund had insufficient assets available to pay claims for a period of 180 days, the compensation program and modification of state tort laws would cease to be effective until sufficient funds to pay all of the claims payable under such Vaccine Trust Fund became available.

Discussion

In General. In signing the legislation that contained the Vaccine Act, President Reagan indicated his support for the goal of compensating persons who suffer injuries as a result of childhood vaccinations. The President, however, also expressed serious reservations concerning the compensation program contained in the Vaccine Act and the financing program that was contemplated but not enacted. The Administration's concerns regarding the compensation program contained in the Vaccine Act are threefold.

First, the compensation program would not serve as the exclusive source of compensation for vaccination injuries, but merely as an alternative, preliminary forum to the tort system. Despite the modifications to the tort system discussed above, it can be expected that many injured persons with potentially large claims, particularly claims for pain and suffering, will continue to resort to the tort system. This would undermine the basic goal of the Vaccine Act to provide equitable compensation to injured persons while enabling manufacturers to produce beneficial vaccines without threat of financial ruin. Inequitable differences in compensation awards would occur depending upon whether a recovery was made through the compensation program or through the tort system. More importantly, the continued exposure of vaccine manufacturers to unpredictable and potentially massive tort liabilities would threaten the ability of manufacturers to continue vaccine production. In this regard, the public health costs of a national shortage of childhood vaccines (as occurred in November 1984 in the case of the DTP vaccine) must be recognized.

Second, the Vaccine Act's compensation program would entail unnecessarily high administrative costs. The payment of attorneys' fees of all successful, and many unsuccessful, claimants would encourage claims of questionable merit or

seriousness. In addition, for the larger claims that would ultimately be pursued through tort litigation, the compensation program would simply represent an additional layer of administrative cost.

Finally, we are concerned by the Vaccine Act's delegation to the Judicial branch of responsibility for administering the compensation program. The judiciary is not well equipped to assume oversight responsibility for the scope or functioning of the program. In addition, delegation of such administrative responsibility to members of the Judicial branch would raise possible constitutional issues regarding the separation of powers.

Source of Funding. Many of the Administration's specific concerns regarding possible methods for financing the Vaccine Act's compensation program reflect broader concerns regarding the basic form of the program as well as the assumption that the program should be financed with Federal tax revenues (either from new excise taxes or existing taxes). As indicated earlier, in several weeks the Administration will propose an alternative no-fault compensation program that should permit vaccine manufacturers to obtain workable insurance arrangements. We believe this approach is consistent with the goal of providing equitable compensation, but will result in a more efficient allocation of costs and benefits. Accordingly, we strongly urge that the issue of how to fund the Vaccine Act be considered in the context of reconsideration of the basic structure of the compensation program itself.

Public Funding Mechanisms. As discussed earlier, the problem of compensating injured persons and properly allocating the costs of such compensation is not limited to childhood vaccines, but exists for a wide range of goods and services. Thus, among our concerns with respect to any public funding mechanism for the Vaccine Act is that it could encourage the creation of similar Federal programs for persons injured by other goods and services.

In addition, a public funding mechanism would supplant market pricing and private insurance as means for providing compensation and allocating the costs of such compensation to the appropriate producers. We do not believe that this is either necessary or appropriate. Among the most serious consequences of this approach would be the loss of appropriate incentives for manufacturers to produce safer vaccines.

Excise Tax. Although the Administration has general objections to any public funding mechanism for the Vaccine Act, funding the compensation program through an excise tax, as contemplated in an earlier version of the legislation, is perhaps the least attractive alternative. First, the creation of a new excise tax would entail substantial administrative costs. The Internal Revenue Service would have to develop new forms, regulations and procedures, while also collecting the tax and auditing vaccine manufacturers. Establishment and operation of the related trust fund would also generate new costs. For example, three separate organizations within the Treasury Department -- the Office of Tax Analysis, Financial Management Service, and the Internal Revenue Service -- share responsibility for making excise tax transfers to a trust fund.

In addition, we are concerned that funding the Vaccine Act's compensation program through an excise tax would create a substantial risk that the program would either operate at a deficit or be unable to compensate many injured persons. Since excise tax rates could be adjusted (other than for inflation) only by Congress, maintenance of an adequate funding level would depend on reasonably accurate predictions of the number and

amount of claims. For a variety of reasons, however, accurate predictions of future claims are highly unlikely.

First, the Vaccine Act's compensation program would provide compensation for relatively minor injuries, since it would require a claimant to show only $1,000 of unreimbursed expenses, standards of proof would be relaxed, and the attorneys' fees of all successful, and many unsuccessful, claimants would be reimbursed. Thus, the compensation program would encourage the filing of many claims that are not filed under the present tort system because of the lack of evidence as to the cause of the injury and the costs of pursuing a tort claim. Second, it is difficult to predict the number of cases in which claimants would resort to the tort system after initially proceeding under the vaccine compensation program. Third, the Vaccine Act covers at least the first 3,500 retroactive cases to file a claim. The actual number of back cases that exist and the amount of claims that might be made are unknown. In addition, as discussed earlier, we are concerned that the costs of administering the program will be higher than expected. Without knowing the number of individuals who would actually receive compensation from the program, the amount of their compensation, or the costs of administering the program, it is impossible to set appropriate excise tax rates.

The danger that the compensation program would be inadequately funded is compounded by the fact that the program would be operated on a pay-as-incurred basis. Under a pay-as-incurred approach, no payment would be made to injured persons for long-term medical care and similar future costs until those costs are incurred. It would thus be difficult to recognize and correct funding deficiencies before they become unmanageable.

The tendency of compensation programs to expand in scope and cost and the difficulty of funding a compensation program with excise tax revenues when outlays are unknown are illustrated by the experience of the Black Lung Disability Trust Fund, the structure of which is similar to that contemplated for the Vaccine Trust Fund.9/ The Black Lung Disability Trust Fund has been operating at a deficit since its initial creation in 1977. As of the end of fiscal year 1986, the Black Lung Disability Trust Fund had paid out $4.979 billion in cash benefits and medical expenses and incurred $328 million in administrative costs. It had also accumulated $1.033 billion in interest costs on repayable advances from the General Fund. During this period, however, the excise tax on coal that was intended to fund this spending produced revenues of only $3.454 billion (other interest receipts totaled $5 million). Consequently, the Black Lung Disability Trust Fund is now $2.88 billion in debt. Under P.L. 99-272, interest accruing on this debt during fiscal years 1986 through 1990 was forgiven.

9/The Black Lung Disability Trust Fund, established under section 9501 of the Internal Revenue Code, provides benefits to individuals and their survivors disabled by pneumoconiosis, Known as black lung disease. The fund is partially funded by an excise tax on the sale of coal (except lignite). The current rate of tax is $1.10 per ton for coal from underground mines and $.55 per ton for coal from surface mines, with a cap of 4.4 percent of the sales price for each ton of coal produced. Individuals and their survivors generally receive payments on a monthly basis.

Lump Sum Trust Fund. The heightened risk of funding deficiencies resulting from operating the Vaccine Act's compensation program on a pay-as-incurred basis could be avoided if all benefits were paid on a lump sum basis. Under this approach, each claimant would receive an annuity contract representing the net present value of all current and projected future costs. Similarly, payments for lost wages and medical benefits to individuals injured before the effective date of the Vaccine Act would be in the form of a lump sum benefit.

Funding a compensation program on this basis would reduce the possibility that claims would greatly exceed revenues in the long-term and ensure injured parties that future benefits would in fact be paid. Moreover, administrative costs would be lower than under a pay-as-incurred approach because the compensation program would deal with each successful claimant on a single occasion, rather than periodically. Despite these relative advantages, if a lump sum trust fund were funded through an excise tax, initial tax rates would be significantly higher than under a pay-as-incurred trust fund.

General Appropriation. An alternative method of providing revenue for the Vaccine Act's compensation program would be through appropriations from the General Fund. The Administration does not support funding a compensation program in this manner. Under the current constraint on government spending, any new program funded from general revenues would divert resources from existing activities. Moreover, appropriations generally can be reduced or eliminated as part of the annual budget process. If the proper funding amount is not fixed or guaranteed on a long-term basis, many injured persons will have little incentive to accept awards under the compensation program, and will be encouraged to pursue claims through the tort system. This would undermine the basic purpose of the compensation program.

In summary, the Administration has serious reservations about the compensation program envisioned in the Vaccine Act as well as any public funding mechanism that might be adopted to finance it. We continue to support the basic objective of the Vaccine Act, however, and will work to produce a fair and responsible program for compensation of persons injured by childhood vaccines.

This concludes my prepared remarks. I would be glad to respond to any questions.

73-717 O = 88 - 2

Chairman RANGEL. Thank you.

Mr. Coyne.

Mr. COYNE. Mr. Ross, if Congress ultimately does decide upon the excise tax route for funding, would it be your judgment that a veto should be recommended by the President.

Mr. Ross. Mr. Coyne, I think that is a very likely outcome, and that would be our recommendation to the President.

Mr. COYNE. Thank you.

Chairman RANGEL. Are there any other questions?

Mr. MATSUI. I just have a brief one. It is somewhat troubling to me because you rule out tax expenditures. You are really ruling out the appropriations process, but yet you still support the basic goals of the program. I wonder if this is a little like the President's support of the drug abuse efforts. He supports the basic concept but he is not willing to put up the funds necessary to make sure those concepts are carried out. What are you suggesting to us today, that you support this but you don't want to fund it?

Mr. Ross. In a sense that is right but we think there is an alternative to funding by the Government of the program. As I said, we intend to propose in a number of weeks just such an alternative.

Mr. MATSUI. If you are talking about some national tort reform or liability reform legislation, you are not going to get it. You just go to the Judiciary Committee and talk to Mr. Rodino and see how far you are going to get. If that is your proposal, you are really barking up the wrong tree. You know that is not going to happen. You have to be pretty logical about this and think reasonably about it and you will realize there are not a heck of a lot of alternatives. If that is out, what would you propose?

Mr. Ross. I wouldn't want to label our proposal as tort reform. My office is not the one primarily responsible for its preparation.

Mr. MATSUI. Then you can't really say anything is going to be initiated in the way of liability reform or anything of that nature.

Mr. Ross. I am confident a proposal will be forthcoming. I am simply not prepared to discuss its details. I think it will be responsive to the basic objectives of the act. It may encounter its own political difficulties and that is something that will be taken into account.

Mr. MATSUI. I think the problem that we have right now is that you ought to at least be candid with us and say you are against this proposal and you are not really in support of the goals because you are not assisting us in a coming up with a way to a achieve those goals. Your alternatives are nonsensical. It is not going to happen in the 100th Congress.

Mr. Ross. I understand your assessment of that. I think I would certainly dispute that our alternative will be nonsensical. We think it will be attractive and have some optimism that it can be realized.

Mr. MATSUI. Go to the Judiciary Committees and ask them first before you come here about whether or not you are going to see any liability reform in the 100th Congress. I think that the kind of proposal you are going to come up with, generally speaking, will not be supported by Mr. Rodino or Mr. Biden. That being the case, I am afraid you are going to have to come back here and give us some assistance. Something is going to happen on this legislation

this year and you ought to be part of it rather than not participating because it will be embarrassing to the President if he has to veto something like this that has such significant health ramifications. You are putting him in that position and he needs some help right now.

Chairman RANGEL. Mrs. Kennelly.

Mrs. KENNELLY. You said the administration's proposal, HHS's proposal would be forthcoming. Can you give us a timeframe, or guess?

Mr. ROSS. I think the best guess, Mrs. Kennelly, would be something like 3 weeks.

Mr. DORGAN. If you are within 3 weeks of sending some kind of proposal to Congress, I think the objections are really on page 9 of your testimony that this could encourage similar Federal programs. My guess is that the root here is in President Reagan's philosophy, that he doesn't want Government involved in much of anything if it helps people. What sort of proposal might we expect within 3 weeks? I assume somebody down there is working on it. Can you give us a general outline of what is expected?

Mr. ROSS. Again, I am not prepared to discuss the details, but in general outline the elements it would contain would be a no-fault compensation structure and we believe designed in a way to enable vaccine manufacturers to obtain private insurance. Beyond that, I am really not prepared to discuss its detail.

Chairman RANGEL. Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman. We held our first hearing on this question 3 years ago and I think the administration at that time told us they were weeks away from some suggestion to us. When they finally came forward with an idea it was to stabilize the liability situation by putting limits on recoveries for those children who were injured and who were able to succeed in getting some judgment in court. In other words, there was nothing in the package to compensate children; just limits on what injured children could recover once they established liability. As I understand, Mr. Ross, you are saying that the administration is not going to go back to that but will instead propose a no-fault compensation system. Is that the broad outline?

Mr. ROSS. That is the broad outline, yes.

Mr. WAXMAN. How would you fund that no fault compensation system?

Mr. ROSS. We believe it could be designed in a way to enable manufacturers to obtain private insurance.

Mr. WAXMAN. You would have them get private insurance to fund it and it would be based on no-fault liability. You are going to redesign the whole thing. You are going to set up the limits on liability. You are going to establish under what circumstances children have a claim and when they don't have a claim.

Mr. ROSS. I assume those sorts of issues will be covered. Since I am not familiar with all of the details and I think some of the specific aspects have not been settled upon.

Mr. WAXMAN. What is the date we will receive this proposal?

Mr. ROSS. My estimate is 3 weeks. That is what I have been told by the people that are preparing it.

Mr. WAXMAN. We would be happy to see what they have to say but the administration has never liked the idea of compensating children who were injured. They always wanted to block off any recoveries children could get when they were successful in court. The whole idea of this bill is to encourage families to go to a compensation system that they know would deal with their problems and not have them go to court as the only option, particularly since so many really do not have a chance in court.

We wanted to make the program voluntary, not mandatory, and I think one of the points we made was there was a concern that families could be able to go to court even if they went to the compensation system. So I suspect what we are going to see from the administration is a proposal that would prohibit families from going to court even if they have a claim that has gone through a compensation system.

I think the administration is going to open up so many issues. My suspicion is it wants to open all these issues so nothing happens and we have the status quo. I hope that is not the case and I will be receptive to something that is constructive. I want to point out we have not had a constructive attitude on the part of the administration for the last 3 years and that the President threatened to veto the bill he actually signed.

Mr. Ross. The President did sign that legislation. I think that indicates his interest in the objectives. Again I would simply suggest that you hold your comment on the administration's proposal until you receive the proposal.

Mr. WAXMAN. There were those urging the President to veto the bill. Secretary Bowen, who endorsed the bill and thought the whole thing was a good idea, urged the President to sign it and he and others in the administration did finally prevail. I think if we now take the last step to make the compensation fund a reality so that the bill will work, then I think some of those same forces in the administration will prevail upon the President again. I think it makes a lot of sense. The whole system makes a lot of sense. Thank you.

Chairman RANGEL. Mr. Ross, if I understand you correctly, who is working on this proposal?

Mr. Ross. No one at Treasury has primary responsibility. I think HHS should be understood as having primary responsibility.

Chairman RANGEL. Who is the expert in the administration that we can talk with?

Mr. Ross. I don't have the name off hand but I can certainly get that. It would be someone at HHS.

Chairman RANGEL. It is my understanding, notwithstanding the fact that the President signed the bill, what you have to come back to the Ways and Means Committee with is going to go far beyond the funding mechanism.

Mr. Ross. It would certainly revisit the structure of the compensation program. There is no question of that.

Chairman RANGEL. That is one way to put it, but you will be undoing the bill the President signed.

Mr. Ross. It would revisit those issues and the President indicated in signing it that he had concerns along that line.

Chairman RANGEL. You understand once we pass a law and the President signs it then we are assigned the responsibility of determining the funding, what you are doing is setting aside an action of the Congress and putting this committee in a position that we can't deal with the mandate that has been given to us by the Congress and to the President.

Mr. ROSS. I understand your point, Mr. Chairman. I think it is the administration's hope that in examining the question of funding this committee and others will have the opportunity to reconsider.

Chairman RANGEL. Why did the President sign the bill in the first place if he didn't like the standards that were in the bill?

Mr. ROSS. I think there are two explanations. One is he did support the basic objectives.

Chairman RANGEL. Everyone supports basic objectives but when the President signs a law he supports what is in the bill.

Mr. ROSS. The second point to that is there was no funding mechanism contained in the legislation and I think he may have honestly believed when funding for the bill was considered, there would be an opportunity to reexamine the nature of the compensation program.

Chairman RANGEL. If it was any other President, I would doubt what you are saying is true but it would make some sense that he would believe that.

Mr. ROSS. Enacting the bill without a funding program probably expressed some ambivalence not only on the part of the President but also on the part of Congress.

Chairman RANGEL. That means we can pass anything we want as long as we don't fund it.

Are there any other questions? Thank you very much.

The next panel will be Dr. Lewis Cooper from my hospital in the 16th Congressional District, St. Luke's Roosevelt Hospital Center. Dr. Cooper is representing today the American Academy of Pediatrics and he will have with him John Butler, Putnam, Hayes and Bartlett. And then we will have Jeff Schwartz from Virginia and he will be representing the parents groups in this area.

I assume that staff has advised the panel that unfortunately we are restricted to the 5-minute rule but in order to make certain that all of your views will be in the record, I ask unanimous consent of the members, and the Chair hearing none, your statements are in the record and we will proceed under the 5-minute rule. Dr. Cooper, welcome to Washington and welcome to the Committee on Ways and Means.

STATEMENT OF LOUIS Z. COOPER, M.D., DIRECTOR OF PEDIATRICS, ST. LUKE'S/ROOSEVELT HOSPITAL CENTER, NEW YORK CITY, ON BEHALF OF THE AMERICAN ACADEMY OF PEDIATRICS

Dr. COOPER. Thank you very much, Mr. Chairman. On behalf of the academy we are very grateful for the opportunity to be here.

You have heard a lot of testimony about the incredible victory that this country has enjoyed in its efforts to conquer vaccine preventable childhood illnesses, and that victory is real. It is of inter-

national acclaim but it is still incomplete, as you know, and even more importantly, it is very fragile. One threat to that victory has been addressed by this legislation. We appreciate the patient caring and wise leadership, some of which is in this room, which brought us this important bill.

The resurgence in measles and pertussis are examples of how real this threat is. It is not a theoretical threat, it is a real one. In New York City we had almost a thousand cases of measles last year. In North Carolina they are experiencing a tremendous resurgence of pertussis.

We had eight cases of congenital rubella syndrome in New York last year. If I close my eyes, I can still hear and see and smell the sounds of a room full of tank respirators with polio victims. We have no intention of going back in that direction. We won't, but we certainly are experiencing needless morbidity and mortality because of the fragility of our vaccine program. Despite the characteristics of the vaccines, we know they are not risk free, and it is clear we must be offering prompt and appropriate help to the unfortunate victims when vaccines do cause damage to children. Since society is the beneficiary of the vaccines, then it is very clear that we as a society have to make an appropriate attempt to compensate the children and their families who are the unfortunate but rare victims of vaccine accidents. The academy was one of the original parties involved in working toward development of this legislation and we feel an obligation to help in the development of a responsible financial plan.

We believe that the law does offer a reasonable funding structure for the vaccine trust fund. However, given our concerns with regard to affordability of vaccine on the one hand and solvency of the trust fund on the other, we think there are several issues that deserve a bit more attention. One of those issues has to do with short-term adverse effects of vaccine. In our testimony, we allude to the issue of shock, collapse or hypotonic-hyporesponsive collapse following DTP vaccine. Briefly, it is our view that the numbers of these episodes are overestimated. While the academy wishes to compensate any victim of a vaccine related reaction, we think specific consideration should be given to elimination of eligibility for compensation for pain and suffering for these temporal reactions. We will be happy to work with the committee in terms of more detail as to what that means.

Since the additional cost of this will ultimately be borne by the parents and the public sector, we must recognize that this comes at a difficult economic period. However, we urge that pragmatic solutions to the funding be developed and be developed now.

I personally was distressed to hear the administration's suggestion of further delay. We can't delay any further. Our vaccine victories are indeed fragile and there do appear to be pragmatic workable solutions. We have seven specific recommendations which are listed in our testimony. Let me highlight several of these.

The system would be funded by a surcharge on each dose of vaccine, levied against the manufacturer, with proceeds going into a national trust fund. We recommend that eligible claimants would receive a lump sum award that would equal the net present value of expected future expenses. We would suggest allowance of pain

and suffering awards only for adverse reactions involving long-term injuries. We would also recommend an increase in the entry limit into the system on unreimbursed medical expenses from $1,000 to $2,500. The surcharges should be initiated 6 months prior to program operation, the payment of past claims should be spread over 30 months of the program and the number of past claims should be limited to 2,000.

The issues are complex. We are grateful for the early attention of your committee and are prepared to provide any assistance in the way of data, discussion, support that we can in order to facilitate the prompt development of a funding mechanism for this very important piece of legislation. Thank you.

[The prepared statement follows:]

STATEMENT OF LOUIS Z. COOPER, M.D., ON BEHALF OF THE AMERICAN ACADEMY OF PEDIATRICS

Mr. Chairman, I am Dr. Louis Z. Cooper, professor of pediatrics at the College of Physicians and Surgeons of Columbia University, and director of pediatrics at the St. Luke's/Roosevelt Hospital Center in New York City. I am here today representing the American Academy of Pediatrics. Accompanying me is Mr. John Butler, a principal of Putnam, Hayes and Bartlett, Inc., who has served as the economic counsel to the Academy on this issue for the past four years. I am pleased to appear before this Committee today and offer the Academy's expertise on an appropriate funding mechanism for the "National Childhood Injury Compensation Program." The funding of this legislation underpins our childhood immunization program and we urge you to move swiftly toward its enactment.

By way of background, our national immunization policy, a cooperative effort between the federal and state governments, has succeeded in drastically reducing the cases of infectious childhood diseases, painful sickness, crippling conditions and death once caused by polio, diphtheria, measles, mumps, tetanus and pertussis (whooping cough). As a nation we can stand proud that 95 percent of all school children are immunized against the major childhood diseases by the time they enter school. We should be proud of our achievements -- but not complacent.

Today we are experiencing a recurrence of these dread preventable diseases, due in part to parents' fears of adverse reactions and to the skyrocketing costs of vaccines. During the first 26 weeks of 1986, the cases of measles rose in this country by 117.6 percent over the same period in 1985. The highest incidence rate occurred among children 0-4 years of age, most of whom were unvaccinated. Some states are already reporting a doubling of cases of pertussis this year. No one can quantify the pain associated with those illnesses. Deafness, blindness, cerebral palsy, retardation and severe emotional disturbances can destroy children and their families. When the capacity to prevent those conditions is at hand, failure to protect our children is doubly cruel.

Yet, even with the proper administration and use of the best vaccine products available today, there is a potential risk of a serious side effect. It is inevitable that one case of polio-like disease will result from each five million doses of polio vaccine, and a serious, permanent neurological injury will result from every 310,000 doses of DTP. In extremely rare cases, an encephalitis or nerve deafness will develop from MMR. Approximately 75 vaccine-related injuries per year are the price we pay to protect the more than 3.8 million children born each year in this country. Society owes these children a great deal for their personal sacrifices. It is unfair to expect parents with children suffering with vaccine-related injuries to traverse the current tort system while shouldering the burden of medical, rehabilitative and other related expenses. Since society is the beneficiary of compulsory immunization laws, it is only fair for society to provide prompt compensation for those few injured in the process.

As one of the principal parties involved in the development of this legislation, we feel obligated to bring to you a responsible financing plan that will meet the objectives of the important program. Basically, these objectives are: 1) to insure a safe and adequate supply of childhood vaccines; 2) to promote more research for even better vaccines; 3) to provide for a fair and just compensation program for those who are injured. Let me say at the outset that no amount of compensation is ever enough for a family whose child has suffered permanent injury or death from a mandated childhood vaccine. However, a fiscally responsible public policy must be developed that fairly compensates those injured children, while at the same time keeps the immunization program affordable for the additional 3.8 million children born each year.

We believe that P.L. 99-660 offers a reasonable funding structure for the vaccine trust fund. However, given the operational and budgetary constraints of trust funds and concerns expressed by the administration and your tax staff, we have explored, in depth, other options. With our overriding concerns of affordability of the childhood vaccines and the solvency of the vaccine trust fund, one issue stands out that merits review by this committee for its cost implications and by the authorizing committee for its policy implications. That issue is the extent to which mild, short-term injuries will be covered.

Shortly after Congress passed the childhood vaccine compensation legislation on October 24, 1986, the staff of the Senate Labor and Human Resources Committee requested that James O. Mason, M.D., the director of the Centers for Disease Control, estimate how many eligible events annually would be caused by vaccines (according to the Vaccine Injury Table that ultimately was included in the new law). One such event is "shock-collapse or hypotonic-hyporesponsive collapse."

Dr. Mason's letter estimates that 9000 such events are caused annually by vaccines containing pertussis bacteria, "probably none with permanent damage." The medical literature cited by Dr. Mason is a study by Cody, et al of the rate of reactions of children to the pertussis vaccine. The study advises that "hypotonic hyporesponsive episode is a descriptive term which (sic) applies to an unusual and characteristic reaction associated with DTP immunization . . . Characteristically, the infant or child [having such a reaction] was pale, hypotonic and unresponsive to . . . parents for a period ranging from 10 minutes to 36 hours. These reactions were associated with the primary immunization series only . . . All [children in the study] returned to normal when evaluated by either their physician or one of the investigators."

The basis for the estimate of 9000 such reactions each year is that nine of some 15,752 children studied following the first DTP immunization developed hypotonic hyporesponsive episodes. Assuming that 90 percent of the 3.8 million children born each year receive five doses of the DTP vaccine, 9000 such episodes are predicted annually.

On the basis of this figure, the Academy is concerned that compensation for hypotonic-hyporesponsive collapse could result in the program becoming excessively costly, particularly if awards include pain-and-suffering benefits. While the Academy wishes that all children who suffer any adverse reaction to a mandated vaccine would be able to benefit from the legislation, it is our opinion that potential awards that could result from compensation on the basis of this relatively minor side effect may jeopardize the stability of the childhood immunization program itself. Thus we recommend careful scrutiny of this issue, with specific consideration given to the elimination of eligibility for compensation for pain and suffering for these reactions. However, if there are residual effects from this type of reaction (for example, if such effects last for more than six months), then we believe that compensation for pain and suffering is appropriate.

We believe that the recommendations here put forth meet the above objectives, with a resulting surcharge on each dose of vaccine that will not adversely impact on the viability of the childhood immunization program. We fully recognize that this additional cost, which will ultimately be borne by parents and public health programs, comes at a difficult economic period, but this is the "bullet we have to bite" to contain the cost of the program.

RECOMMENDATIONS

1. The system would be funded by a surcharge on each dose of vaccine levied against the manufacturer, with proceeds going into a national trust fund.

2. Eligible claimants would receive a lump-sum award that would equal the net present value of expected future expenses. The lump-sum award would be used to purchase an annuity that would provide the claimant with guaranteed payments over his or her lifetime.

3. Allow pain-and-suffering awards only for adverse reactions involving long-term injuries. By including pain and suffering for the mild reaction cases, the annual cost of the program would almost triple in cost, placing an unsatisfactory surcharge on each dose of vaccine.

4. Increase the entry limit on unreimbursed medical expenses from $1000 to $2500. We feel that this amount is a more reasonable point of entry into the compensation system and eliminates coverage of short-term reactions.

5. Stagger the surcharge and compensation program by six months so start-up costs can be covered without borrowing.

6. Pay past claims over the first 30 months of the program to reduce surcharge inequities.

7. Limit the number of past claims to 2000. We feel this is a more realistic number and such reduction would help ensure the solvency of the fund.

We thank you for your interest in this legislation and pledge to you our support in working on a responsible funding mechanism.

Chairman RANGEL. Thank you. We really appreciate your offer to assist us because the funding mechanism unfortunately deals with the substance of the bill in many cases. Mr. Butler.

STATEMENT OF JOHN C. BUTLER III, PRINCIPAL, PUTNAM, HAYES & BARTLETT, INC., ECONOMIC COUNSEL TO THE AMERICAN ACADEMY OF PEDIATRICS, AND MERCK & CO., INC.

Mr. BUTLER. Thank you, Mr. Chairman.

I request permission to enter my full statement into the record. However, I will just briefly summarize my cost analysis of the compensation program.

Chairman RANGEL. Without objection.

Mr. BUTLER. I will estimate the size of the vaccine surcharge needed to create a wholly self-financing compensation program.

I will also outline for the committee two choices it has if it wishes to cut program costs.

Now to estimate the cost of a compensation program, the committee needs to determine three factors. First, the number of cases and type of cases eligible for compensation; second, the number of past cases eligible for compensation; and third, the amount of compensation for each type of eligible claim past or future.

I used the legislative framework in the statute to guide my analysis. However, my analysis differs from the statute in one important respect. I assume claimants would receive a lump sum award. The statute assumes a pay-as-you-go approach.

In my opinion, the lump sum award would be more attractive to claimants since future payments are not contingent on reauthorization of funds for the vaccine compensation program by Congress. In addition, the compensation program itself could use the lump sum award to purchase, from private insurers, an annuity which would provide guaranteed payments over the claimant's lifetime.

In preparing my cost estimates, I used the latest available data from the Centers for Disease Control and the Department of Health and Human Services. I grouped vaccine reactions into three broad categories for purposes of my cost analysis. They are deaths, chronic cases involving long-term injury lasting more than a year, and mild reaction cases not involving long-term injury. Using the CDC data, the number of claims expected is 11 deaths per year, 62 chronic cases per year, and over 9,000 of the mild reaction cases per year.

With this information, I estimate the 5-year cost of the statutory program to be $513 million. This program would provide compensation for those suffering long-term injury or death and those 9,000 or so mild reaction cases.

If awards for the mild cases were to be reduced by providing compensation for just net medical cost and lost earnings, then the 5-year cost would drop from $513 million to $305 million.

If compensation were provided to only those suffering long-term injury or death, that is no mild cases would receive any compensation, 5-year costs would be $225 million rather than $513 million. This amount is less than one-half the statutory program costs. These costs are not distributed evenly in time. The first year costs

are higher because sufficient revenue is needed to pay for past claims.

If the committee wishes to cut program costs, in my opinion it has two choices. First, it could eliminate compensation for the 9,000 or so mild reaction cases or, second, it could reduce the compensation amount paid to mild cases by paying for only unreimbursed medical costs and economic damages.

My written testimony outlines several specific changes you might consider in this regard.

In addition, I believe prudent financial management would require the CDC incidence estimates to be increased by 25 percent to account for any possible underreporting of adverse reactions. It would also be prudent to stagger the surcharge and compensation parts of the program by 6 months, so the need to borrow start-up costs can be avoided. I would also recommend payment of past claims be spread out over 2½ years so that the initial surcharge could be reduced.

Implementing these suggestions would result in a 5-year program cost of $280 million, if compensation were provided only to those suffering long-term injury or death, or about $380 million if the mild reaction cases are added, if medical expenses and lost earnings are allowed for those cases. These costs are substantially less than the $513 million costs of the statutory program.

My cost estimates and the vaccine surcharges that would result are included in my testimony on pages 11 and 12. Finally, in my written testimony I show that the program with these surcharges could be solvent under a wide range of conditions.

Mr. Chairman, this concludes the summary of my testimony. I would be happy to answer any questions.

[The prepared statement follows:]

TESTIMONY OF
JOHN C. BUTLER, III
PRINCIPAL
PUTNAM, HAYES & BARTLETT, INC.

COST OF THE NATIONAL VACCINE COMPENSATION PROGRAM

I am John C. Butler, III and I am a Principal of Putnam, Hayes & Bartlett, Inc., (PHB). PHB is an economic and management consulting firm specializing in analysis of economic issues concerning the environment, energy, product liability, antitrust, and international trade among other issues. My professional experience has centered on public policy analysis of product liability and environmental issues. Prior to joining PHB, I was employed by the World Health Organization, the United Nations Environment Programme, and the Environmental Protection Agency. Since 1984, I have been engaged by the American Academy of Pediatrics to estimate the cost of vaccine compensation legislation. Today, I will summarize my analysis of the likely cost of a vaccine compensation program and estimate a vaccine surcharge to create a self-financing program. I will also outline several choices this Committee has to reduce the cost of a vaccine compensation program.

I. INTRODUCTION

In 1986, approximately 46 million vaccines were administered to children to immunize them against such diseases as tetanus, diphtheria, pertussis, polio, measles, mumps, rubella, and others under mandatory vaccination programs. These immunization programs save many children from disability and death, as well as protect society in general from disease epidemics. However, each year a small number of children have severe reactions to vaccines that result in permanent disability and, in some cases, even death.

Legislation signed by the President last year (referred to as PL 99-660) established a program to compensate victims of adverse reactions following immunization. This program will not take effect until Congress passes legislation to fund the National Vaccine Compensation Program. I use the legislative framework described in PL 99-660 as a basis for forecasting the cost of the program. However, my cost analysis differs from PL 99-660 in one important way. The statute assumes claimants would be paid expenses as incurred on an annual basis. Payments for anticipated future expenses would not be made for a period in excess of one year. In my analysis, it is assumed claimants would receive a lump sum award which would equal the net present value (NPV) of expected future expenses, including lost earnings. The National Vaccine Compensation Program could use the lump sum award to purchase from private insurers an annuity which would provide the claimant with guaranteed payments over his lifetime.

The pay-as-incurred approach as contemplated in PL 99-660 would defer future payments, for example, lost earnings, until those costs were incurred, thus lowering initial funding requirements relative to a lump sum approach. In later years, however, the cost of the pay-as-incurred approach would greatly exceed the lump sum approach as many claimant cohorts begin to receive compensation for lost earnings. A lump sum approach would help ensure the Program's solvency since it would discharge its responsibility to a claimant when an award was made. Further, a lump sum award should be attractive to claimants since payments of future expenses would not be contingent on reauthorization of the vaccine surcharge by Congress.

II. SUMMARY OF FINDINGS

To estimate the likely cost of the program, the Committee needs to determine:

- The number of cases of each type of illness category that would receive compensation.
- The compensation cost per case for each type of illness category.
- The number of past cases and the compensation these cases would receive.

Once the cost of the Compensation Program is known, then the Committee can determine an appropriate vaccine tax rate to pay for the Program.

Number of Claims Expected

The Vaccine Injury Table in PL 99-660 determines the type of presumptively compensable injuries. I have grouped the injury claims into three categories: deaths, chronic cases (i.e., cases involving long-term injury lasting more than one year), and mild reaction cases (i.e., cases not involving long-term injury). According to the latest data and information available from the Centers for Disease Control (CDC), Department of Health and Human Services, and in consultation with the American Academy of Pediatrics, I assume the following annual incidence of adverse reactions following immunization:

	Annual Incidence*
Deaths	11
Chronic cases with long-term injury	62
Mild reactions not involving long-term injury	9,150

Most mild reaction cases (98 percent) involve shock collapse, which is described as a shock-like episode where the patient is unresponsive for 10 or more minutes, but does not suffer paralysis or seizures.** In addition, I assume that 946 past cases, which is equal to one-half of the long-term injuries or deaths expected to be associated with vaccines during the last 22 years, would receive compensation for future medical expenses as described in the statute.

Cost Per Case

The lump sum costs per case, including the cost of reasonable attorney fees and program administrative costs, are as follows:

	Present Value Cost***
Death	$280,000
Chronic cases	$478,000
Mild reaction cases	$ 25,300

In cases involving death of an infant, the cost includes a $250,000 payment to the family plus attorney fees and administrative costs. The distribution of cost among compensation components such as pain and suffering, medical expenses, and lost earnings is quite different for mild reaction cases and chronic cases, as shown in Exhibit 1. Lost earnings account for 47 percent of chronic case costs, while pain and suffering accounts for 21 percent. In the mild reaction case, pain and suffering accounts for 60 percent of total costs.

Compensation Program Cost Projections

To establish the likely cost of the legislation, I developed three principal scenarios.

---

* See Exhibit 5 for more detailed information on incidence assumptions and reference sources of assumptions.

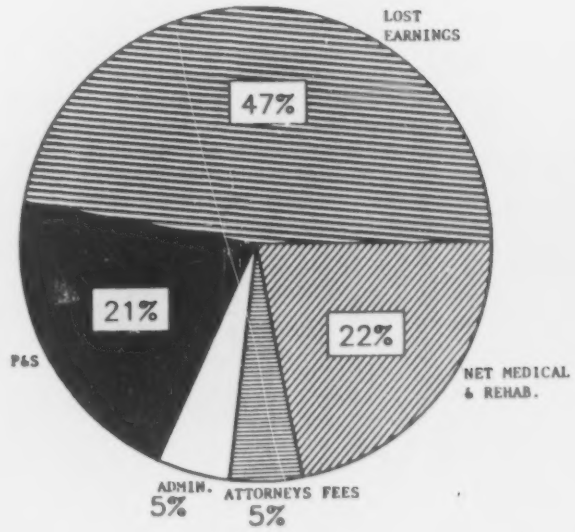
** See Pertussis Vaccine Injury: AMA Ad Hoc Panel on Pertussis Vaccine Injury, JAMA, Dec. 6, 1985 - Vol. 254, No. 21.

*** See Part III of testimony, which describes cost assumptions.

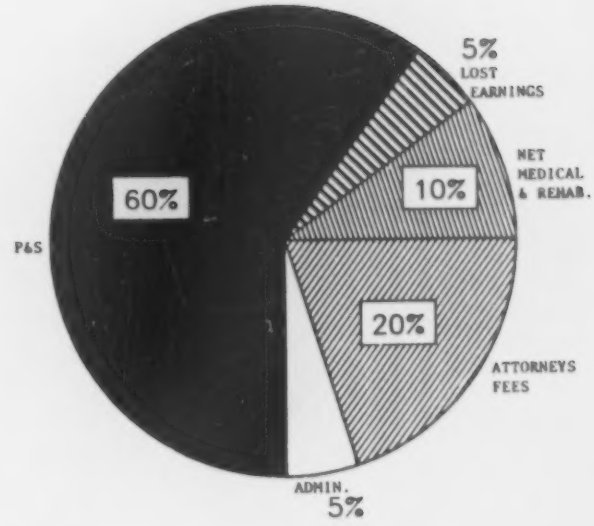
Exhibit 1

COST COMPARISON

CHRONIC CASE



MILD CASE



- Core Case, which compensates only vaccine reactions involving long-term injury or death.
- Mild Reaction Case, which is the Core Case plus compensation for reactions not involving long-term injury.
- Mild Reaction Case but pain and suffering payments are only awarded to claimants sustaining long-term injuries.

As the statute is currently drafted, the second scenario -- the Mild Reaction Case -- most closely represents how the Program might be implemented. The five year NPV cost and the annual cost of each scenario is given in Exhibit 2. High first year costs result from my assumption that all past claims are paid in the first year. Costs in later years cover vaccine injuries or deaths that occur in those years. The cost of the PL 99-660 Program is $196 million in the first year, $110 million in the second year, and costs increase with inflation in subsequent years. This cost is almost three times the annual cost of the Core Case. The Mild Reaction Case (i.e., the PL 99-660 Program cost) has a five year cost of $513 million which is more than double the five year Core Case cost.

As shown in the exhibit, when pain and suffering awards for the mild reaction cases are eliminated, as in the third scenario, costs are substantially reduced. Annual costs for this scenario are only one-half the annual costs of the Mild Reaction Case, which includes pain and suffering payments to mild cases.

Vaccine Surcharge

The vaccine surcharge needed to raise sufficient revenue to cover the cost of each scenario is shown in Exhibit 3. First year surcharges are very high because sufficient revenue is needed to pay for past claims. The second year surcharges are much lower and subsequent years' surcharges would increase with inflation. In the Mild Reaction Case, the first year surcharge for DPT and MMR exceeds $7, which is 66 percent and 41 percent of the private sector cost of each vaccine, respectively. In the second year, the DPT and MMR surcharge is 37 percent and 23 percent of the current vaccine cost, respectively.

Number of Past Claims

One factor that could substantially affect Program cost is the number of past claims receiving compensation. I assume that 946 claims, which is one-half of the long-term injuries or deaths expected to be associated with vaccines during the last 22 years, would receive compensation. If the maximum number of past claims (3,500) allowed by PL 99-660 were paid, and no mild reaction cases received compensation, then the five year cost of the Program would double the Core Case cost. If 2,000 past claims are paid and mild cases are included (i.e., the PL 99-660 Program with 2,000 past cases rather than 946), then the five year cost would be about $600 million.

Conclusions

The most likely five year cost of a compensation program patterned after PL 99-660 would be about $513 million. Given the uncertainty which affect these cost projections, I believe it is possible for the PL 99-660 Program costs to approach $600 million, but that they are unlikely to exceed that value.

A number of options are available to reduce the cost of the Vaccine Compensation Program and the size of the vaccine surcharges, and still compensate children severely injured as a result of vaccination. Congress has two basic choices in my opinion. First, Congress could decide to compensate only those children sustaining long-term health injury or death. This would substantially reduce the most likely five year cost of the Program from $513 million to $225 million. I also suggest that Congress consider reducing the limit on past claims from 3,500 to 1,500. This would contribute to financial stability and predictability of Program costs. Second, if Congress wants to retain compensation for the mild reaction cases, I recommend the Committee consider the following:

Exhibit 2

ANNUAL VACCINE
COMPENSATION PROGRAM COST
($ Million)

	Year 1	Year 2	Year 3	Year 4	Year 5
Core Case (5 yr. NPV = $225)	$125	$36	$37	$39	$41
Mild Reaction Case: PL 99-660 (5 yr. NPV = $513)	$196	$110	$114	$119	$124
Mild Reaction Case, No Pain and Suffering (5 yr. NPV = $305)	$145	$56	$58	$61	$64

Exhibit 3

VACCINE SURCHARGES
(Cost Per Dose)

	$ Core Case		Mild Reaction (PL 99-660)		Mild Reaction, No P&S	
	Year 1	Year 2*	Year 1	Year 2*	Year 1	Year 2*
DPT	$4.79	$1.38	$7.54	$4.22	$5.56	$2.17
DT	.06	.02	.10	.05	.07	.03
MMR	4.67	1.34	7.34	4.11	5.41	2.11
Polio	.31	.09	.49	.27	.36	.14

The surcharge variation by vaccine is based on the relative incidence of adverse reactions as described in the Waxman bill (HR 5546).

* Subsequent years' surcharges increase with inflation.

- Allow pain and suffering payments only for adverse reactions involving long-term injury or death.
- Reduce the limit on past claims from 3,500 to 1,500.
- Reduce the number of mild reaction claims by raising the limit on unreimbursed medical expenses for entry to the Compensation Program from $1,000 to $2,500.

For both the above alternatives, the payment of past claims should be spread over the first 30 months of the Program to reduce the size of the initial vaccine surcharges. Implementing these changes would substantially reduce the cost of the Program. In addition, to ensure the solvency of the Program, I believe it would be prudent to:

- Increase the estimate of the number of claims expected to be paid by 25 percent to account for possible underreporting of reactions,
- Stagger the surcharge and compensation parts of the Program by six months so start-up costs can be covered without borrowing from the Treasury.

Following the above suggestions, I estimate the per-dose surcharge for each option would be:

	Alternative 1		Alternative 2	
	Years 1,2,3	4th Year	Years 1,2,3	4th Year
DPT	$2.94	$1.86	$3.73	$2.92
DT	.04	.02	.05	.04
MMR	2.86	1.81	3.63	2.85
Polio	.19	.12	.24	.19

Alternative 1 provides compensation to those suffering severe injury or death. Alternative 2 adds mild reaction cases to Alternative 1.

The surcharge in subsequent years would increase with inflation. The five year cost of the revenue streams for Alternatives 1 and 2 is expected to be $280 million and $378 million, respectively. This is substantially less than the most likely cost of the PL 99-660 Program ($513 million).

Exhibit 4 shows the Vaccine Compensation Program revenues, costs, and cash balances using the above assumptions for Alternative 2. Even if 25 percent more claims are paid than expected, a positive cash balance of $2 million would result. If the number of claims paid were equal to the CDC incidence assumptions, then the cash balance would be given by the curve labeled Expected Cash Balance. The size of the expected cash balance is the safety margin on the solvency of the Program. As the Exhibit indicates, the Vaccine Compensation Program with the suggested vaccine surcharges could remain solvent under a wide range of conditions.

III. APPROACH FOR ESTIMATING PROGRAM COSTS AND VACCINE SURCHARGES

In this section, I will describe the methodology and data sources used in the analysis of program costs and calculation of vaccine surcharges. There are three key determinants of the cost of the vaccine compensation program. These include:

- Number and type of cases eligible for compensation,
- Number of past cases eligible for compensation, and
- Scope and magnitude of compensation for future and past cases.

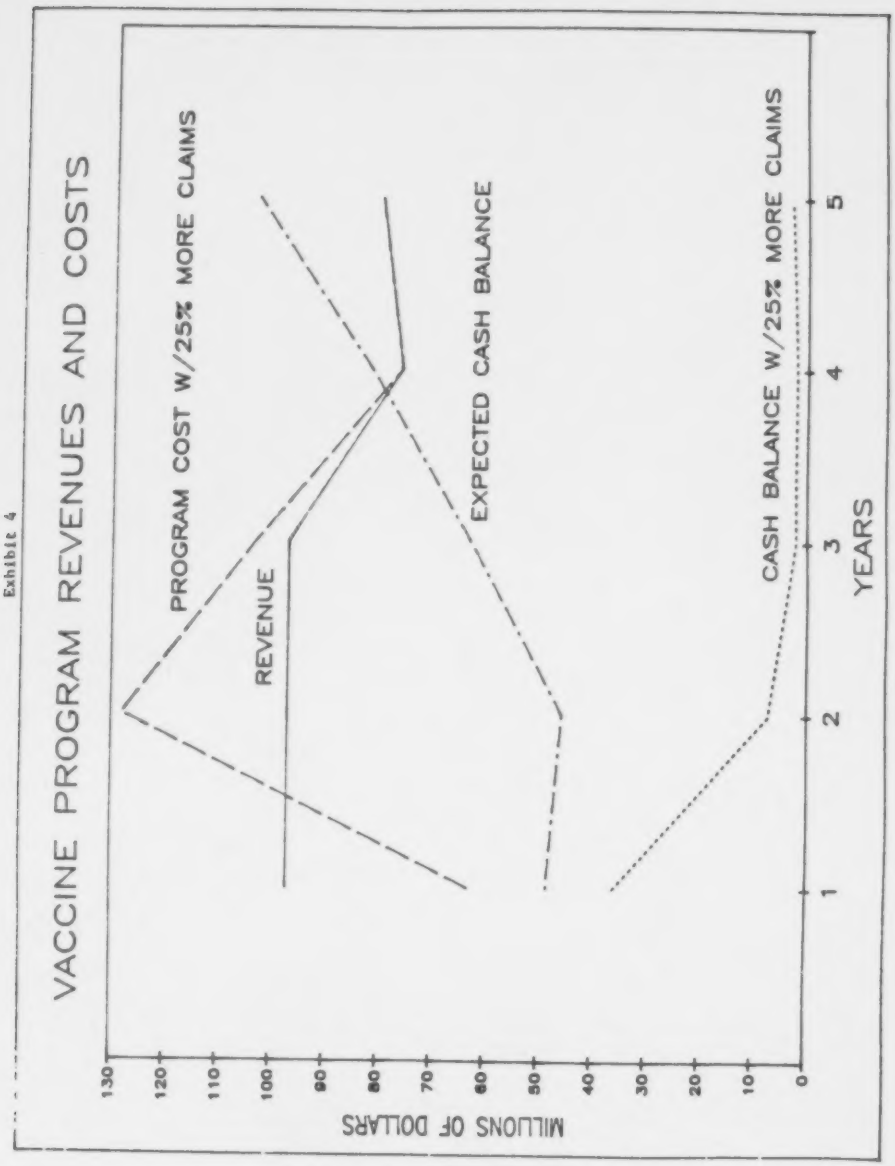
A. Number and Type of Cases Eligible for Compensation

The number of claims likely to be filed for compensation of adverse reactions to the vaccines covered by PL 99-660 is not known with certainty. Several parties, including the Center for Disease Control (CDC), the

---

* A similar exhibit for Alternative 1 (not shown) shows the same conclusions, that is, the Program with the suggested surcharges could remain solvent under a wide range of conditions.

Exhibit 4


VACCINE PROGRAM REVENUES AND COSTS
PROGRAM COST W/25% MORE CLAIMS
REVENUE
EXPECTED CASH BALANCE
CASH BALANCE W/25% MORE CLAIMS
MILLIONS OF DOLLARS
130
120
110
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
YEARS

American Medical Association (AMA), and the American Academy of Pediatrics (AAP), have attempted to estimate the frequency of various types of adverse reactions. I identified three major categories of reactions: deaths, chronic cases, and mild reaction cases as described earlier. All of these categories of reactions would be eligible for compensation under PL 99-660.

The annual incidence of fatalities associated with vaccines used in our analysis is derived from data collected by the CDC's "Monitoring System for Adverse Events Following Immunization (MSAEFI)."* The CDC survey is primarily limited to patients who received vaccines paid for by the public sector. The CDC reported 25 deaths following public sector vaccinations during 1982-1984. Thirteen deaths during this three year period were determined to be caused by conditions unrelated to vaccination. After adjusting the 12 remaining deaths by the fraction of vaccine doses administered in the public sector, I determined that approximately 11 fatalities per year would be associated with vaccinations in the public and private sectors.

Chronic cases that could be compensable injuries under PL 99-660 include the following clinical categories of reactions as reported by the CDC: arthritis and arthralgia, convulsions - febrile, convulsions - non-febrile, encephalitis, and other neurological disorders. To determine the number of claims filed, I use the Assistant Surgeon General's estimate of the number of cases with long-term health impairment.** These estimates show that approximately 62 chronic cases (54 encephalopathies resulting in permanent damage and eight cases of permanent paralysis) are presumed to be associated with vaccines and would be eligible for compensation based on the Vaccine Injury Table in PL 99-660.

For the number of injuries not involving long-term impairment, that is, the mild cases, I again use the Assistant Surgeon General's figures to determine the number of claims. These figures show that approximately 9,150 mild reaction cases per year would be expected. The vast majority of these cases (9,000) are categorized as hypotonic/hyporesponsive shock collapse reactions, while encephalopathy without long-term injury (100) and anaphylaxis (50) constitute a relatively small portion. In addition, since the number of mild reaction cases is so large, one should also consider the number of severely retarded individuals that would be expected from all causes in a sample population of this size. (Under the Program, these individuals might be able to recover compensation even though their retardation was not caused by a vaccination.) The President's Committee on Mental Retardation reports that approximately 0.158 percent of children born each year in the United States are either severely or profoundly retarded. Employing this frequency figure, I estimate that, on average, about 14 of 9,150 mild reaction cases would be severely or profoundly retarded. I assume that the cost per case for these children is similar to the cost for claimants who have long-term injuries.

B. Number of Past Cases Eligible for Compensation

Past incidence is expected to be proportionally higher because more children were immunized. My study assumes an incidence rate for chronic cases of 73 per year for 22 years prior to enactment. Twenty-two years of past cases is used because DPT, polio, and measles vaccines were not widespread until 1964. I also assumed past incidence of 13 fatalities per year for each year prior to enactment. Fifty percent of past cases are assumed to actually file claims and receive benefits under the compensation system. That is, 946 claims for past injuries or deaths would be paid. No past cases involving mild reactions are expected, since these cases would not incur medical expenses lasting more than one year and, thus, are not eligible for compensation under PL 99-660. The incidence assumptions and the number of claims expected are summarized in Exhibit 5.

---

* Adverse Events Following Immunization: Surveillance, Centers for Disease Control, December 1986.

** Letter to Mr. Doug Campbell, Senate Labor and Human Resources Committee, from Dr. James D. Mason, Assistant Surgeon General and Director of Center for Disease Control, October 24, 1986.

C. Scope and Magnitude of Compensation for Future and Past Cases

Six different compensation components are outlined in the legislation:

- Medical Expenses.
- Rehabilitation, Home Care, and Other Continuing Services.
- Earnings Loss.
- Pain and Suffering.
- Survivors Benefits.
- Legal Fees.

In addition to these cost components, there is a cost associated with the administration of the program.

Medical Costs and Rehabilitation Services

All medical and rehabilitation costs are based on work done by the Office of Technology Assessment (OTA) and by A.D. Little for the National Center for Health Services Research (NCHSR) of HHS. Medical costs cover hospital care, inpatient specialist, outpatient specialist, and outpatient non-specialist care. Rehabilitation costs include cost of home modification, physical therapy, long-term care, and equipment. A 1986 Putnam, Hayes & Bartlett, Inc. report documents many of the assumptions. The key assumptions are summarized here.

NCHSR developed 73 "Resource Utilization Profiles" that describe a range of patient scenarios, medical, and rehabilitation resource requirements for 18 clinical categories of vaccine reactions. Within each clinical category, scenarios range from mild to severe. NCHSR also estimated the net present value (NPV) cost, assuming a 2.5 percent real discount rate, of all medical and rehabilitation costs for each resource utilization profile. The cost variability is great between mild and severe scenarios. These estimated costs, which are reported in 1980 dollars, have been inflated by the annual medical care price index to reflect 1986 medical costs.

Data on the actual distribution of cases within a clinical category in terms of the severity of vaccine reactions are not available. Based on phone interviews with several experts in pediatric neurology and immunization and infectious diseases, the distribution of cases within each category is assumed to be symmetric. That is, the average cost within each category can be represented by the midpoint of the cost range. Several neurologists believe that the distribution of cases may be skewed toward the lower cost side in several clinical categories. Hence, average costs in those categories would be less than the midpoint estimate. However, the midpoint of the cost range is used as a conservative point estimate of actual medical and rehabilitation costs for chronic cases.

The CDC, through its monitoring system (MSAEFI), collects data on the reported incidence of various types of vaccine reactions in the public sector. Based on the relative incidence rates reported in these data and the cost estimates derived from the OTA and NCHSR reports, a weighted average cost estimate of $129,289 (NPV) per chronic case was calculated. I assumed that this cost estimate was based on a life expectancy of 40 years, resulting in an average payment of $5,150 per year. I assumed the claimant would receive this payment, but have a normal 73 year life expectancy. Hence, the average NPV of medical and rehabilitation costs

---

* Office of Technology Assessment, Compensation for Vaccine-Related Injuries, Table 1, pp. 42-43, November 1980.

** HHS, Estimated Economic Costs of Selected Medical Events Known or Suspected to be Related to the Administration of Common Vaccines. "Resource Utilization Profiles." Unpublished Appendix, April 1981.

*** Estimated Costs of "The National Childhood Vaccine Injury Compensation Act," Putnam, Hayes & Bartlett, Inc., June 1986.

Exhibit 5

ANNUAL INCIDENCE OF ADVERSE REACTIONS

CASES WITH LONG-TERM HEALTH INJURY		62*
DEATHS		11**
TOTAL "MILD" REACTIONS (i.e., reactions not involving long-term injury)		9,150*
Hypotonic/hyporesponsive	9,000	
(Severe or profound retardation-- 14)		
Encephalopathy without long-term injury	100	
Anaphylaxis	50	

Past Incidence Is 73 Long-Term Injury Cases And 13 Deaths Per Year For 22 Years Prior To Enactment. Only 50 Percent Of Past Cases Are Assumed To File Claims.

---

* Letter to Mr. Doug Campbell from James D. Mason, Assistant Surgeon General and Director of Center for Disease Control, October 24, 1986.

** Derived from data in CDC report, Adverse Events Following Immunization, December 1986.

based on a 73 year life expectancy would be $172,049. This is also a conservative assumption.

As a basis for estimating the medical and rehabilitation costs for mild reaction cases, I employed a cost range of $53-$14,267 as reported in the HHS study. Because most of these cases are expected to be at the lower end of the cost range, a cost distribution with a $3,000 average cost and with 95 percent of the values in the range of $600 to $7,200 was chosen to represent mild reaction medical costs. I believe this distribution is more likely to overestimate rather than underestimate medical costs. Analysis of this cost distribution reveals that one could expect about 30 percent of the 9,150 mild reaction cases to incur unreimbursable costs greater than $1,000 and, hence, be eligible for compensation. In making this estimate of the percentage of eligible claims, I have specifically taken into account the portion of children expected to receive health insurance benefits.

For those mild reaction claims eligible for compensation under PL 99-660, I estimate the unreimbursed medical costs would average approximately $2,130 (total medical costs would average about $4,700). In addition to these mild reaction case medical costs, I account for compensation of severely and profoundly retarded individuals expected among the "mild" cases using exactly the same procedure as outlined for chronic cases. Compensation under PL 99-660 is subrogated to third-party reimbursement, such that the net cost of the program is reduced by that portion of medical and rehabilitation costs covered by private insurance and other public compensation programs. Approximately 86 percent of the U.S. population under 18 years of is are covered by some form of private insurance or public compensation program, including Medicare, Medicaid, Disability Insurance, Social Security Insurance, private insurance policies, employee family plans, etc. An average of 77 percent of long duration medical and rehabilitation costs are covered by these programs. Therefore, approximately two-thirds of all medical and rehabilitation cost would be covered by other reimbursement programs and only one-third would have to be paid by the Vaccine Compensation Program. I used this insurance data to determine the amount of unreimbursable medical expenses for mild reaction claims. However, it is questionable whether or not third-party insurance will cover all long-term medical and rehabilitation costs, particularly the cost of long-term custodial care. Therefore, I have assumed that third-party insurance will cover an average of only 40 percent of all medical and rehabilitation costs for long-term injuries.

Earnings Replacement

All chronic cases involving permanent impairment and/or disability are eligible for compensation for lost earnings beginning at age 18 and ending at age 65. The lost earnings component of PL 99-660 is based on the 1986 average private, non-farm sector annual earnings of approximately $19,000, with specified offsets. I have assumed an offset of one-third, which is consistent with other income replacement programs such as workers' compensation. The replacement of only two-thirds of lost income is because this income is not taxable and because a portion of the claimant's living expenses are covered by other components of the compensation package. Mild cases are not eligible for lost earnings since, by definition, they incur no long-term impairment and/or disability.

Pain and Suffering

All chronic cases are eligible for a pain and suffering award of up to $250,000. I assumed that pain and suffering awards will average $100,000 per case. This award is assumed to be paid in a lump sum amount at the time of settlement. For mild cases, I assumed pain and suffering payments

---

* These figures have been inflated to 1986 dollars using the Medical Care Price Index.

** Health Insurance Association of America, Source Book of Health Insurance Data, 1984-1985.

would average $15,000.* Alternative pain and suffering awards were also examined. Claimants who received the vaccine prior to 1987 would not be eligible for a pain and suffering award.

Survivors benefits in the case of a vaccine-related fatality are set at a level of $250,000, according to the legislation. This payment is assumed to be paid in a lump sum amount to the family of the victim in the year of the victim's death.

Other Costs

PL 99-660 also allows for compensation to cover reasonable attorneys fees and other costs incurred in proceedings on the claim. For chronic cases, I assume legal fees average six percent of total compensation, which comes to about $25,000. For mild cases, I assume attorneys fees average $5,000 when $15,000 pain and suffering awards are granted, and $2,500 when no pain and suffering awards are granted.

In addition to the cost components explicitly stated in the legislation, there will be costs associated with the administration of the program. Administrative costs under the Black Lung Program have averaged approximately 6.2 percent per year over the past six years; however, the Black Lung Program's definition of administrative costs includes several items that would not be covered by this legislation. Therefore, a six percent cost for administering the vaccine compensation program is a relatively conservative assumption.

The basic assumptions used to estimate program costs are summarized in Exhibit 6 for chronic and death cases and in Exhibit 7 for mild reaction cases.

In Exhibits 6 and 7, the NPV for each cost component of chronic, death, and mild cases is summarized. The total NPV cost per chronic case is $477,715, per fatality is $280,000, and per mild case, including the cost of the retardation cases, is $25,331. Lost earnings comprise the largest portion of total costs for chronic cases (47 percent). For mild reaction cases, pain and suffering is the largest component, comprising 60 percent of total costs. Exhibit 1 (page 3) illustrates the relative costs of each compensation component for chronic and mild cases.

The total costs per case are based on a lump sum payment to the claimant in the year the case is filed. For chronic victims who have a 73 year lifetime this lump sum payment could provide $7.9 million over the claimants lifetime. If the claimant lived only 50 years, then the cash payments would equal approximately $3.2 million (see Exhibit 8).

D. Vaccine Compensation Program Cost Projections

I begin developing my cost estimates by determining program costs -- using the assumptions described earlier -- for the following scenarios:

- The Core Case, which compensates only vaccine reactions that result in long-term injuries or death.
- The Mild Reaction Case, which is the Core Case costs plus compensation for reactions not involving long-term injury.
- The Mild Reaction Case costs with pain and suffering awards only to those cases involving long-term injury or death.

All of the above cases assume that 946 past claims will be paid.

---

* In jury trials involving medical expenses of several thousand dollars, non-economic damages typically average four to five times economic damages. Hence, a $15,000 pain and suffering award is a reasonable assumption since medical costs for eligible mild reaction claims average about $4,000.

Exhibit 6

COST ASSUMPTIONS FOR CHRONIC AND DEATH CASES

	Chronic NPV*	Death NPV*
Medical & Rehabilitation Costs	$172,049	$ 0
Insurance Coverage @ 40 percent	68,820	0
Net Medical & Rehabilitation Costs	103,229	0
Lost Earnings	223,302	0
Pain & Suffering	100,000	0
Survivors Benefits	0	250,000
Subtotal	$426,532	$250,000
Administrative Costs	25,592	15,000
Attorneys Fees	25,592	15,000
Total	$477,715	$280,000

* Net present value costs are estimated using a 2.5 percent real discount rate.

Exhibit 7

COST ASSUMPTIONS FOR MILD REACTION CASES

Average Unreimbursed Medical Cost Per Eligible Claim	$ 2,130
Pain and Suffering Payments Per Eligible Claim	15,000
Administrative Costs (6 percent of Compensation)	1,028
Attorneys Fees	5,000
Total	$23,158*

Retarded Cases receive the same compensation as Chronic Cases.

* For cases without pain and suffering, the attorneys fees are $2,500 and total costs are $4,758.

Exhibit 8
LIFETIME VALUE OF LUMP SUM AWARD

A LUMP SUM AWARD OF $450,000 COULD PROVIDE CASH PAYMENTS TO A CLAIMANT IN EXCESS OF $7 MILLION OVER THE CLAIMANT'S LIFETIME.

	Cash Payments*	
	73 Year Life	50 Year Life
Medical Costs	$2.2 million	$0.7 million
Lost Wages	5.6 million	2.4 million
Pain and Suffering	0.1 million	0.1 million
	$7.9 million	$3.2 million

* Cash payments are estimated by applying a five percent interest rate to the lump sum award. Applying a higher interest rate, which is quite realistic, would result in higher lifetime cash payments.

The estimated total NPV of Program costs for the Core Case over the first five years of the Program is $225 million. The total cost of the Program in the first year is $125 million, since all past cases are assumed to be reimbursed in the first year. The second year annual cost of the Program is $36 million, which will increase with inflation in future years. The NPV for the first five years of cost when mild reaction cases are included is $513 million. First year cost is $196 million. The second year annual cost is $110 million, and subsequent years will increase with inflation. Limiting pain and suffering awards to only adverse reactions involving long-term injuries or death substantially reduces five year Program costs from $513 million to $305 million (see Exhibit 2, page 5).

Exhibit 2 shows the annual cost for each scenario. As illustrated in the exhibit, compensating mild cases more than doubles the five year Program costs. Annual costs after the first year (i.e., after past claims have been paid) almost triple Core Case annual costs. Limiting pain and suffering payments to only those cases with long-term damage reduces annual Program costs to 55 percent above Core Case costs.

I examined several other Program cost scenarios. These are:

- Maximum number of past claims, which is the Core Case except that 3,500 past claims are paid rather than 946 (no mild cases).
- Mild Reaction Case with no pain and suffering payments to mild cases except that 3,500 past claims for long-term injury or death are paid.
- Mild Reaction Case with pain and suffering awards and 2,000 past claims.
- Core Case with pain and suffering payments of $250,000 to chronic cases, no compensation to mild cases.
- Mild Reaction Case with no pain and suffering payments to mild cases but increase the number of chronic, death, mild, and past cases by 25 percent.
- Core Case, no compensation for mild cases, but increase the number of chronic, death, and past cases by 25 percent.

The cost implications of all scenarios examined are presented in Exhibit 9. As first year costs include payment of past cases, second year costs are more indicative of future costs, which will increase with inflation over the course of the Program.

The Core Case assumes that 946 past claims for long-term injury and death will be paid. If 3,500 past claims are paid, then the five year NPV cost ($450 million) is double the cost of the Core Case. If 3,500 past claims are paid and mild cases are included without pain and suffering awards, then five year costs reach $530 million. However, based on the CDC incidence estimates, I would expect that no more than 2,000 long-term injury and death cases would result from past vaccinations. If 2,000 past claims are paid and mild cases are included, then the five year NPV cost is about $600 million.

If pain and suffering awards for long-term injuries average $250,000 -- the maximum allowed in PL 99-660 -- then annual costs would increase by about 30 percent (i.e., $11 million in the second year). Total five year costs of the Core Case would increase by about 20 percent. The last two scenarios show that a 25 percent increase in the number of claims increases costs by 25 percent.

Vaccine Surcharges

The vaccine program may be financed by a surcharge levied on all vaccine manufacturers. According to HR 5546 -- which included a funding mechanism which was not enacted -- this vaccine surcharge would be added to the cost of each vaccine in proportion to the number of adverse events

---

* 73 chronic cases per year plus 13 deaths per year times 22 years of past large-scale vaccinations equals 1,892 cases.

associated with that vaccine. HR 5546 assumed that 77 percent of all serious vaccine injuries are believed to be caused by vaccines containing the pertussis antigen. Therefore, I assumed the surcharge on vaccines containing the pertussis antigen whould account for approximately 77 percent of total revenues.

Adopting the HR 5546 approach for relating the surcharge to vaccines, and using the dose information provided below, the dose surcharge can be determined for each cost scenario.

	1985 Doses Distributed
DPT	19,800,000
DT	1,000,000
Polio	20,700,000
MMR	5,000,000

Exhibit 3 (page 5) lists the surcharge for three of the vaccine cost scenarios.

IV. CONCLUSIONS AND RECOMMENDATIONS

The most likely five year cost of a Vaccine Compensation Program patterned after PL 99-660 would be about $513 million. If 2,000 past claims were paid (about twice the number I expect), then five year costs would be about $600 million. I believe it is possible but not likely that the five year costs would exceed $600 million.

Congress has two basic choices if it wishes to reduce the cost of the Program and still accomplish the Program's primary objectives. Congress can either eliminate mild reaction cases from the Compensation Program entirely (Alternative 1), or it can limit the amount of compensation paid to mild reaction cases (Alternative 2). Providing compensation only to those children suffering long-term injury or death would substantially reduce the most likely five year cost of the Program from $513 million to $225 million. I would also suggest that Congress consider reducing the limit on past claims from 3,500 to 1,500. This would add financial stability to the Program.

If Congress wants to maintain compensation for mild cases, I would recommend the following actions be undertaken:

- Eliminate and suffering payments for mild reaction cases. Such payments would be available for those suffering long-term injury.
- Reduce the maximum number of past claims from 3,500 to 1,500.
- Raise the limit on unreimbursed medical expenses for entry to the Compensation Program from $1,000 to $2,500.

To reduce the size of the initial surcharge, the payment of past claims could be spread out over the first two-and-a-half years of the program. Also, revenue estimates might prudently be set to cover 25 percent more claims than actually forecasted based on CDC incidence data. Finally, the surcharge could begin six months before the Compensation Program pays claims so the need to borrow start-up costs is avoided.

If these changes were adopted, the vaccine surcharges for each alternative shown in Exhibit 10 would generate sufficient revenue to keep the program solvent under a wide range of conditions (see below). The five year NPV cost of the expected revenue streams of each aiternate is $280 million and $378 million, respectively.

Solvency of Vaccine Trust Fund

A key objective of the Vaccine Compensation Program should be to ensure that it is self-financing. That is, the financial projections for revenues and costs should show positive cash flow for the entire period of operation. The Program's cash flow should be of sufficient magnitude to

Exhibit 9

PROGRAM COSTS FOR ALTERNATIVE SCENARIOS
($Millions)

	5 Year NPV	Year 2 Annual Costs
Core Case (no mild cases)	$225	$ 36
Mild Reaction (S 1744 case)	$513	$110
Mild Reaction, no pain and suffering (P&S) to mild cases	$305	$ 56
3,500 past claims, no mild cases	$450	$ 36
3,500 past claims, mild cases without P&S	$530	$ 56
Mild reaction case with P&S; 2,000 past claims	$606	$110
Core Case with $250,000 P&S to chronic cases	$268	$ 47
Mild Reaction case, no P&S to mild cases, 25% increase in all claims	$378	$ 70
Core Case (no mild cases), 25 percent increase in all claims	$278	$ 45

Exhibit 10
VACCINE SURCHARGE
(Per Dose Charge)

	Alternative 1		Alternative 2	
	Year 1,2,3	Year 4*	Years 1,2,3	Year 4*
DPT	$2.94	$1.86	$3.73	$2.92
DT	.04	.02	.05	.04
MMR	2.86	1.81	3.63	2.85
Polio	.19	.12	.24	.19

Alternative 1 provides compensation to those suffering long-term injury or death. Alternative 2 adds mild reaction cases to Alternative 1.

The surcharge variation by vaccine is based on relative incidence of adverse reactions as described in HR 5546.

---

* The surcharge would increase annually with inflation in subsequent years.

account for short-term reductions in revenue and short-term increases in vaccine injury compensation.

To evaluate cash flow, I examine Alternative 2 and estimate the revenue stream, the Program costs, and the interest on unspent cash balances. Using the tax rate assumptions listed in Exhibit 10 for Alternative 2 and the expected vaccine dosages listed earlier, the revenue would be $97 million for each of the first three years and $76 million and $80 million in the fourth and fifth years, respectively.

Exhibit 4 (page 7) shows the Compensation Program revenues, costs, and cash balances for Alternative 2. The revenues are constant for the first three years while past claims are paid. In the fourth year, the revenue decreases about 22 percent and increases thereafter with inflation. The Program costs, assuming 25 percent more claims are paid than expected, is listed in the exhibit. Even though this cost exceeds revenues in the second and third years, sufficient cash is available to pay all claims and Program administration costs, and leave a $2 million cash balance. (See curve labeled Cash Balance w/25% More Claims.) If the number of claims filed were to equal our incidence assumptions, then the Program cash balance in any year would be given by the curve labeled Expected Cash Balance. The magnitude of the expected cash balance is the safety margin on the solvency of the Program. If the Program cash balance were as large as the Expected Cash Balance, then the vaccine surcharge may be reduced in later years. (Similar conclusions would apply to a cash flow analysis of Alternative 1.)

The vaccine tax shown in Exhibit 10 for Alternative 2 generates sufficient revenue to pay the following claims and remain solvent:

- 78 claims per year for long-term injury when we expect 62 claims.
- 14 death claims per year when we expect 11 claims.
- 3,440 mild reaction claims when we expect no more than 2,750 claims.
- 1,180 past claims when we anticipate about 950 claims.

The Alternative 1 tax generates sufficient revenue to pay for all the above claims except for the mild reaction cases, which would not be compensated in Alternative 1. Hence, the Vaccine Compensation Program with the suggested surcharges could remain solvent under a wide range of conditions.

Chairman RANGEL. Thank you. Whom do you represent, Mr. Butler?

Mr. BUTLER. I started working on the cost of a vaccine compensation program for the American Academy of Pediatrics in 1984. In fact, I was introduced to the academy by Mr. Jeff Schwartz, president of Dissatisfied Parents Together. In 1986, I updated the 1984 cost study. The 1986 study was sponsored by the academy and three drug companies; Merck, Lederle, and Connaught. My most recent work which is reflected in today's testimony has been sponsored by the academy and Merck.

Chairman RANGEL. Now we hear from the Dissatisfied Parents Together, Mr. Schwartz.

STATEMENT OF JEFFREY H. SCHWARTZ, PRESIDENT, DISSATISFIED PARENTS TOGETHER

Mr. SCHWARTZ. Thank you, Mr. Chairman.

I am Jeff Schwartz. I am the president of Dissatisfied Parents Together, and I appear here today on behalf of that group.

We, like the academy, joined in support of the initial legislation. We are here today to assist the subcommittee in devising appropriate funding legislation. Our group calls itself Dissatisfied Parents Together because our children have been killed or permanently brain damaged by legally mandated childhood vaccines. The law said we had to give these vaccines to our children supposedly to protect their health, but the law did not see to it that these vaccines were as safe as they possibly could be. And when our children suffered instead of benefitted from these vaccines, the law, at least until recently, turned its back and looked away.

The timing for this hearing is particularly poignant for our family, Mr. Chairman. Last week my wife and I should have celebrated the sixth birthday of our daughter Julie. Instead, later this month, we will be paying our third anniversary visit to her grave. She died as a result of a vaccine-induced seizure disorder that began within hours of her third DPT shot. But it is not just our family that grieves. Families from every State in the United States have joined this mom and pop group when they discovered their children too had been permanently disabled or died from the side effects of mandated vaccines. So for 5 years this group has struggled to care for our children who survive, to hold our families together, to mourn the lost lives and dreams and potential that have been needlessly squandered, and to get the Government and the medical community to acknowledge the existence—and to honestly determine the magnitude—of this dark side of the mandatory vaccination program. We also have been pushing for safer vaccines and greater safety to prevent needless injuries in the future. Please understand, Mr. Chairman, we are not an antivaccine group. Our voice in support of getting safer vaccines and a safer system to prevent these injuries gradually is being heard.

Last year Congress passed Public Law 99-660 which included the vaccine injury compensation program. Now, this subcommittee faces this difficult question:

How should the system be funded?

We want to be as constructive as possible, and we don't want to be dogmatic about exactly how to fund the system. So we prefer to lay out some principles that we would like to see reflected in this legislation.

First, the new legislation needs to reflect facts, not fantasy, facts as to how many children really are permanently disabled and killed by mandated vaccines, not wishful thinking and fatally flawed studies or so called passive data bases that foolishly minimize the size of this problem, facts that spotlight the unjustified profits and unsubstantiated claims of some vaccine makers who have told the Congress that they had to raise DPT prices by almost 10,000 percent because of the so-called liability crisis, but tell their shareholders there is no problem, and then say they are setting aside a liability reserve of $8 per dose, yet that liability reserve apparently does not exist anywhere except in the bottom line as profits, facts as to whether there really is, or ever was, a liability crisis; and facts as to whether these vaccine makers will voluntary roll back their enormous price rises if the compensation system is funded to head off the so-called crisis. Will they really bring down the price if we rely on them voluntarily to do it?

Secondly, funding should be available for all children who have been seriously injured or killed by these vaccines, not only for those injuries and deaths that occur in the future.

I want to highlight a third point, Mr. Chairman, because this is the point that Mr. Waxman and the Treasury spokesman made and we agree strongly. Funding sources have to be reliable and adequate to pay for a lifetime of around the clock care for these multiple handicapped individuals who can't care for themselves. Unless the funding sources are reliable and assure compensation for the lifetime of the child, parents have no practical alternative but to seek compensation through the tort system.

Fourth, the funding mechanism should provide for lump sum settlements. Here I think there is broad consensus forming, or fully funded annuities backed by the U.S. Government, so that parents who are inclined to do so can confidently elect to receive compensation for their children in lieu of pursuing court cases.

Fifth, the funding mechanism needs to be reasonably prompt and result in an up or down decision. Under the law there is no enforceable deadline for compensation decisions to be made and thus the process can drag on for years. The new funding mechanism should not tamper with the law's existing safeguards. Nor should it reopen all the questions the administration wants to reopen. We have been begging the administration for positive proposals for years and we turned to the Congress only out of despair that we could never get anything from them. The tort remedy, the right of the parents to sue in the event of negligence, wrongdoing, unreasonably dangerous vaccines, or inadequate compensation must be preserved. The new funding mechanism should strengthen, not undercut, the incentives for development and use of safer vaccines.

This point, too, has to be stressed. The best way to reduce the economic costs of this program in the future is to stop the occurrence of preventable vaccine-induced deaths and disability. You have been told that a handful of kids get injured inevitably. We ask you to look behind that assertion because we think the facts

73-717 O - 88 - 3

show that a number of these cases are preventable. They could have been prevented with stronger safeguards. We want you not to fund this new law in a way that takes away its safeguards.

Time limits preclude listing all our concerns here. We would be pleased to submit our more full statement for the record.

We do want to conclude by expressing our desire to work with the staff and the subcommittee. We do think constructive proposals can be forthcoming and we do want to stand in support of properly crafted legislation, but we will strongly oppose any attempt to further restrict the parents' right to go to court to sue to protect our children's right. We ask this subcommittee to limit the scope of this legislation so it will focus on fair, adequate, reliable and appropriate funding sources and techniques for the compensation part of the law.

We urge you, too, don't assume when there is a compensation system that works that the manufacturers will bring their prices down. They have told the other subcommittees that they can't or won't do that. We ask you to look, as part of the function of this bill, to bringing down the prices. Ask the question: Why are the prices as high as they are? What is the real cost of this product? It looks like the cost of producing pertussis vaccine is 2 percent of the price which means 98 percent is going somewhere else. Where? Where, if there is no real liability reserve?

There are a number of questions that need to be asked.

We come here primarily to say we think constructive funding approaches can be found. There are a variety of funding mechanisms that can be used. We are concerned about a funding mechanism like leaving it to year-to-year appropriations. We don't want to have to fight a political battle each year, and I don't see how in good conscience we can advise our parents to give up their right to go to court and sue in return for a yearly fight to see whether or not they can get their children's health care needs met.

We really appreciate the chairman's leadership on this issue and the subcommittee's interest and we stand ready to work with you constructively on this legislation.

[The prepared statement and attachment follow:]

Dissatisfied Parents Together (DPT) 128 Branch Road, Vienna, VA 22180 (703) 938-DPT3

TESTIMONY BEFORE THE SUBCOMMITTEE
ON SELECT REVENUE MEASURES,
HOUSE COMMITTEE ON WAYS AND MEANS
March 5, 1987

Jeffrey H. Schwartz, President
Dissatisfied Parents Together (DPT)

Mr. Chairman, and Members of the Subcommittee:

My name is Jeffrey H. Schwartz. I am President of Dissatisfied Parents Together (DPT), and I appear here today on behalf of that group.

Mr. Chairman, we welcome this Subcommittee's consideration of alternative means of funding the newly-enacted vaccine injury compensation law. We appreciate the invitation to appear before you today. In our testimony, we will briefly:

- o explain who Dissatisfied Parents Together is; and
- o set forth the major principles that we believe should guide the development of legislation to fund the vaccine injury compensation system.

I. DISSATISFIED PARENTS TOGETHER

Our group calls itself Dissatisfied Parents Together because our children have been killed or permanently brain-damaged by legally mandated childhood vaccines. The law said we had to give these vaccines to our children, supposedly to protect their health. But the law didn't see to it that these vaccines were as safe as they possibly could be. And when our children suffered, instead of benefited, from these vaccines, the law--until recently--turned its back and looked away.

The timing of this hearing is particularly poignant for our family, Mr. Chairman. Last week, my wife and I should have celebrated the sixth birthday of our daughter, Julie. Instead, later this month we will be paying our third anniversary visit to her grave. Three years have passed since she died as a result of a vaccine-induced seizure disorder that began within hours of her third DPT (diphtheria-pertussis-tetanus) shot.

But it is not just our family that grieves. Families from every state in the United States have joined this "Mom & Pop" group, when they discovered their children, too, had become permanently disabled or had died from the side effects of mandated vaccines.

For nearly five years, we have struggled:

- o to care for the children who survive;
- o to hold our families together, financially and emotionally;
- o to mourn the lost lives, dreams, and potential that have been needlessly squandered, and to comfort each other and our children;
- o to get the government and the medical community to acknowledge the existence--and to honestly determine the magnitude--of this dark side of the mandatory vaccination program;
- o to push for safer vaccines, and greater safety in the way we produce, test, and administer current vaccines.

We are not an anti-vaccine group. We long for the availability in the U.S. of a less-reactive pertussis (i.e., whooping cough) vaccine, as Japan has used effectively since 1981. And we believe parents should have the right to conscientiously object to mandated vaccines which needlessly jeopardize the lives and health of our children.

Gradually, our voice is being heard. In November 1986, the Congress enacted Public Law 99-660, which included a national childhood vaccine injury compensation and safety program. While that law differed in several significant respects from what our group had sought, it did

represent the first official acknowledgement of these vaccine-injured children.

II. WHERE DO WE GO FROM HERE?

Now this Subcommittee faces the next difficult question: How should the new compensation system be funded? We offer what we believe is a constructive approach. We will refrain from rigid adherence or opposition to any particular funding mechanism. We would like to work with this Subcommittee and staff to develop an appropriate approach.

We do offer, however, the following eight major principles that, in our view, should be reflected in this funding legislation:

1. First, the new legislation should reflect facts, not fantasy...

   - facts as to how many children really are permanently disabled and killed by mandated vaccines, not wishful thinking, fatally flawed studies, or so-called passive "data bases" that foolishly minimize the size of this problem;

   - facts to spotlight the unjustified profits and unsubstantiated claims of some vaccine makers, who told the Congress they had to raise DPT vaccine prices by almost 10,000% because of the so-called "liability crisis," but who told their shareholders, "no problem";

   - facts as to whether there really is (or ever was) a vaccine "liability crisis"; and

   - facts as to whether vaccine makers will voluntarily roll back these enormous price rises if the compensation system is funded to head off this so-called "crisis."

2. Funding should be available for all children who have been seriously injured or killed by these vaccines, not just those whose injuries or deaths occur after enactment of this enabling legislation.

3. Funding sources should be reliable and adequate to pay for a lifetime of round-the-clock care for these multiply handicapped individuals who cannot care for themselves.

4. The funding mechanism should provide for lump sum settlements or fully-funded annuities backed by the U.S. Government, so that parents who are inclined to do so, can confidently elect to receive compensation for their children in lieu of pursuing tort remedies against vaccine manufacturers.

5. The funding mechanism should assure a reasonably prompt up-or-down decision on the compensability of the claim. (Under P.L. 99-660, there is no deadline for compensation decisions to be made and thus the process may drag on for years.)

6. The new funding law should not tamper with existing safeguards of P.L. 99-660 which are critical to the integrity, fairness, and workability of that scheme. These critical safeguards include:

   - preservation of parents' right to sue vaccine makers and doctors in cases involving negligence, unreasonably dangerous vaccines, or compensation results which are inadequate to meet the injured child's needs;

   - assuring that compensation decisions in specific cases will be made by a politically-independent and secure entity specially suited to adjudicate claims; and

- assuring that any change to state tort law resulting from P.L. 99-660 only becomes effective with respect to specific claims for which there is adequate and reliable compensation system funding available to meet lifetime care needs of these disabled individuals.

7. The new funding mechanism should strengthen, not undercut, the incentives for development and use of safer vaccines. The best way to reduce the economic costs of this program in the future is to stop the occurrence of preventable vaccine-induced deaths and disabilities.

8. The new funding mechanism should reflect the fact that both the government and the vaccine makers have been responsible for these preventable injuries. For nearly 25 years, both government and the industry have known that the only existing "safety test" for pertussis (whooping cough) vaccine is basically irrelevant to the vaccine's potential to cause brain damage or death. During this same period, FDA standards have allowed the marketing of pertussis vaccines with as much as 2700% variation in potency. Neither industry nor the government has done much to develop a new safety screening test or tighter quality control measures.

Time limits preclude listing all our concerns here. We would be pleased to submit supplementary comments in writing. We would also be pleased to meet with Subcommittee members and staff to help define a mechanism or mechanisms that can meet these concerns and the legitimate concerns of others being voiced today.

III. CONCLUSION

Mr. Chairman, Dissatisfied Parents Together stands ready to support and help enact properly-crafted legislation to fund the vaccine compensation part of P.L. 99-660. But we will strongly oppose any attempt to further restrict parents' rights to go to court to sue to protect our childrens' rights. So long as a lawsuit is an option, we can keep the pressure on for development and use of the safest possible vaccines for future children. So long as a lawsuit is an option, we can hold accountable those whose negligence or callous indifference have led to our children's deaths and disabilities. So long as a lawsuit is an option, we can assure that any compensation system is a real alternative to the fault-based system, not another way of denying the problem or attempting to sweep it cheaply under the rug and out of sight.

So we implore this Subcommittee to limit the scope of this implementing legislation. We hope it will focus on fair, appropriate, reliable, and adequate funding sources and techniques for the compensation part of the law. We hope you will also question the legitimacy of the exorbitant price rises which a few companies have imposed on the taxpayer and powerless consumers who are mandated by law to buy this product, no matter what the cost. We urge you to confer subpoena power on GAO to get all pertinent information from all manufacturers and suppliers of mandated childhood vaccines.

Neither the government, nor "private industry" should be able to hide behind a veil of secrecy when the issues relate to the safety and fair pricing of these mandatory "public health" products. We urge this Subcommittee to mandate a full independent investigation of the real basis for the drastic increase in vaccine prices (when only 2% of the price reflects production costs).

For further information, contact:

Barbara Fisher
938-3783 (leave message)
or
Jeff Schwartz
783-3388

ORIGINAL ARTICLES

Neurologic complications in oral polio vaccine recipients

Between April 1982 and June 1983 four children 3 to 24 months of age were referred for evaluation of neurologic abnormalities found to be compatible with vaccine-related poliovirus infection, which had not been suspected by referring physicians. Patients were epidemiologically unrelated residents of Indiana, and none had prior symptoms suggestive of immunodeficiency. All had received poliovirus vaccine orally (first dose in three, fourth dose in one) and a diphtheria-tetanus-pertussis injection in the left anterior thigh within 30 days of symptoms. A vaccine-like strain of poliovirus was isolated from each patient, and each had symptoms (left leg paralysis in three; developmental regression, spasticity, and progressive fatal cerebral atrophy in one) persisting for at least 6 months. Immune function was normal in two with poliovirus type 3 infection, and abnormal (hypogammaglobulinemia, combined immunodeficiency) in two with type 1 and type 2 infection, respectively. The incidence of observed vaccine-related poliovirus infection in Indiana recipients of orally administered poliovirus vaccine was 0.058 per 100,000 per year, significantly greater ($P < 0.001$) than predicted. (J Pediatr 1986;108:878-881)

John W. Gaebler, M.D., Martin B. Kleiman, M.D., Morris L. V. French, Ph.D., Gordon Chastain, B.S., Charles Barrett, M.D., and Charles Griffin, B. S.

From the Section of Infectious Diseases, Departments of Pediatrics and Pathology, Indiana University School of Medicine, and the Indiana State Board of Health, Indianapolis

Current knowledge of the risk of poliomyelitis and the rates of vaccine-associated complications is required to determine whether the live or the inactivated poliovirus vaccine is optimal for control of poliomyelitis.[1] In the United States, calculation of the risk of vaccine-associated complications has relied on practicing physicians recognizing and reporting cases to state and local health departments, and ultimately to the Centers for Disease Control. From 1969 to 1981, the "best available paralytic poliomyelitis case count" compiled by the CDC averaged four cases per year among recipients of orally administered poliovirus vaccine.[1] Although the risk to adult OPV recipients and adult contacts of vaccinees is recognized by most physicians, the risk to presumably healthy infant vaccine recipients is not generally appreciated. We have recently recognized four cases of vaccine-related neurologic complications in infant vaccine recipients. All four occurred between April 1982 and July 1983 in Indiana, a state with a population of 5.5 million. In each instance the referring physician failed to associate the neurologic abnormality

See related article, p. 1031.

BAPPCC	Best available paralytic polio case count
CT	Computed tomography
DTP	Diphtheria-tetanus toxoid-pertussis vaccine
IPV	Inactivated poliovirus vaccine
OPV	Orally administered poliovirus vaccine

Supported in part by the James Whitcomb Riley Memorial Association

Submitted for publication July 27, 1984; accepted Feb. 28, 1986.

Reprint requests: Martin B. Kleiman, M.D., Director, Pediatric Infectious Disease, James Whitcomb Riley Hospital for Children, 702 Barnhill Dr., Indianapolis, IN 46223.

Volume 108
Number 6

with administration of OPV; referring diagnoses included trauma in two, spinal cord tumor, and failure to thrive.

CASE REPORTS

Patient 1. In March 1983, this previously healthy 1-year-old boy had fever, irritability, and left leg weakness 22 days after the initial dose of DTP (left anterior thigh) and OPV. The onset of symptoms was associated with minor trauma. In the ensuing 4 days, fever resolved and he became unable to walk, crawl, or sit. On admission the only abnormality was flaccid left leg paralysis; sensation was normal. The cerebrospinal fluid contained 23 WBC/mm³; glucose concentration was 54 mg/dl, and protein 131 mg/dl. Serum IgA was 69 mg/dl (normal 19 to 55 mg/dl), IgM 124 mg/dl (31 to 77 mg/dl), and IgG 796 mg/dl (442 to 880 mg/dl). Serum complement, T and B cell quantitation, T cell subsets, phytohemagglutinin lymphocyte stimulation, somatosensory evoked responses, and computed tomography of the head all yielded normal results. Poliovirus type 3 was isolated from stool and throat, and was characterized by the van Wezel and Hagendonk[2] method (performed at the CDC) as similar to Sabin strains. Serum obtained 3 to 10 weeks after paralysis had neutralizing activity of ≥1:40 against poliovirus type 3. A complement fixation antibody titer against *Mycoplasma pneumoniae* was 1:64, 1 week after admission, and had fallen to 1:8 within 21 days. Cold agglutinin titers were ≤1:4 in both serum specimens. Cultures for *M. pneumoniae* were not done. Two years later the leg flaccidity and muscle atrophy persisted; development and growth were otherwise normal. A complete series of IPV was given, after which neutralization titers to poliovirus types 1 and 3 were ≥1:40. Serum neutralizing antibody activity failed to develop during and after completion of the IPV series.

Patient 2. In April 1982, 2 weeks after receiving a fourth dose of DTP (left anterior thigh) and OPV, this 2-year-old boy had fever and left arm and leg weakness. Until this illness, the patient had been completely healthy and had never had any illness or infection suggestive of an immunodeficiency disorder. On admission 6 days later he had left hemiparesis, with greatest weakness in the leg. No other significant abnormalities were found on physical examination; normal lymphoid tissue was present. The cerebrospinal fluid contained 19 WBC/mm³; protein concentration was 60 mg/dl, and glucose 71 mg/dl. CT of the head yielded normal findings. The ECG demonstrated a focus of slow activity in the right central and temporal regions. Poliovirus type 1 was isolated from the nasopharynx, and was characterized by the CDC as Sabin-like by the van Wezel technique. Sera obtained 1 and 2 weeks after the onset of paralysis had poliovirus type 1 neutralization titers of 1:10. Neutralization titers to types 2 and 3 were <1:10. Serum IgA was 2 mg/dl (normal 26 to 74 mg/dl), IgG 50 mg/dl (553 to 971 mg/dl), and IgM 12 mg/dl (27 to 73 mg/dl). Mumps and *Candida* skin tests produced reactions. Peripheral blood lymphocytes included 3% B cells; T cells, T cell subsets, and helper/suppressor ratio were normal. Two months later the left arm weakness had resolved and the ECG was normal. Flaccid paralysis and muscle atrophy of the left leg persisted. Intravenously administered gammaglobulin therapy was begun. The patient has remained in good health, with infrequent, mild respiratory tract infections, and the paralysis has persisted. He continues to require gammaglobulin supplements for humoral immunodeficiency.

Patient 3. This 9-month-old boy was referred for evaluation of failure to thrive and developmental regression in June 1982. At 6 months he sat alone, attempted to crawl, and babbled. He received doses of DTP and OPV at 4 months, and again at 6 months of age. At 7½ months he became listless, verbal activity decreased, and spontaneous use of the left arm and leg decreased slightly. Complete evaluation for failure to thrive and slow development at 8 months of age concluded with a diagnosis of cerebral palsy of undetermined origin. At admission he was alert, did not verbalize, and had spastic quadriparesis with decreased use of the left side. Cerebrospinal fluid, CT of the head, and nerve conduction velocities were all normal. An ECG showed mild generalized cerebral hemispheric dysfunction. Serum IgA concentration was <0.3 mg/dl (normal 19 to 55 mg/dl), IgG 7 mg/dl (442 to 880 mg/dl), and IgM 2.4 mg/dl (31 to 77 mg/dl). Blood lymphocytes were 16% T cells and 38% B cells; T cell subsets were 15% T4 and 28% T8. T cell response to phytohemagglutinin was markedly depressed. Poliovirus type 2, characterized by the CDC as Sabin-like, was recovered from stool and throat within 24 hours of tissue inoculation; high titers (10^6/ml) of poliovirus were recovered from both sites until death. Virus was not isolated from cerebrospinal fluid. The serum IgG was maintained at 400 to 600 mg/dl with intravenously administered gammaglobulin supplements. At 19 months, CT showed profound bilateral cerebral atrophy, most marked in the frontal and temporal regions. Neurologic and respiratory function progressively worsened, and the patient died at 21 months. Permission for postmortem examination was refused.

Patient 4. This previously healthy 3-month-old boy demonstrated left leg weakness in July 1983. He was referred to a community hospital for evaluation of a possible spinal cord tumor. Four weeks earlier he had received initial DTP (left anterior thigh) and OPV. The only abnormality at examination was flaccid left leg paralysis; sensation was intact. Lumbar puncture was not done. Poliovirus type 3 (CDC) was isolated from stool. Serum IgG concentration was 375 mg/dl (normal 311 to 549 mg/dl), IgA 49 mg/dl (8 to 34 mg/dl), and IgM 52 mg/dl (19 to 41 mg/dl). T cell numbers and function were normal. Neutralization titers against type 3 poliovirus were ≥1:32, 2 and 4 weeks after the onset of paralysis. Paralysis and left leg atrophy persisted at 18 months; growth and development have otherwise been normal.

DISCUSSION

The criteria used for including cases in the BAPPCC are illness clinically and epidemiologically compatible with poliomyelitis, paralysis, and persistent neurologic deficit after 60 days.[1] Patients 1, 2 and 4 fulfilled these criteria. Clinical and laboratory findings in our patients were comparable to those of the BAPPCC. The CDC reported a male/female ratio of 2.7:1 in vaccine recipients. Eleven of

the 37 vaccine recipients in the BAPPCC were immunodeficient, as were two (patients 2 and 3) of our four patients. Paralysis occurred in the leg in which the DTP was administered in our patients with paralysis; such localization of paralysis by wild polio infection after intramuscular injection has been reported.[3] No such data exist for vaccine strains. Paralysis was in a lower limb in 93% of the patients in the BAPPCC. Evidence for vaccine polio infection as the cause of illness in patient 3 is not definitive. This patient would not have fulfilled the criteria for inclusion in the BAPPCC. His findings were strikingly similar to those in a published report[4] of a child with combined immunodeficiency in whom progressive hypertonia and regression of social and motor development resulted from persistent poliovirus infection; poliovirus was isolated from throat and stool but not from CSF, which was normal. At autopsy, a strain of poliovirus type 2 with some dissociation of antigen and neurovirulence markers was recovered from brain tissue. Because permission for autopsy could not be obtained in our patient, and thus we were unable to examine or culture neural tissue, the diagnosis could not be firmly established.

The relative advantages and disadvantages of IPV and OPV have been extensively reviewed.[5] The major disadvantage of OPV is the potential risk of neurologic complications in vaccine recipients and susceptible contacts. The dramatic reduction of the number of cases of endemic and epidemic poliomyelitis in the United States has served to increase the proportion of cases that are vaccine associated. From 1971 to 1981, the BAPPCC included 153 cases of poliomyelitis.[1] Of these, 37 occurred in vaccine recipients, 56 in susceptible contacts of vaccine recipients, and 60 were either sporadic, imported, or epidemic cases that could not be associated with vaccine usage. The 37 neurologic complications among vaccine U.S. recipients yielded an annual incidence of 0.002 per 100,000 population. In Indiana, we observed an annual incidence of 0.058 per 100,000 ($P = 0.006$), remarkably higher than expected for the 15-month interval. The 1980 census estimated the Indiana birth rate to be 85,000 live births per year. A survey by the Indiana State Board of Health in 1980 reported that 88% of children younger than 2 years of age had received three or more doses of OPV. Based on a similar birth rate and immunization practices, the risk of neurologic complications among vaccine recipients younger than 2 years of age was approximately one in 37,500 for the interval during which our patients were observed. This differed with the estimate of two or three per million vaccinees reported by others.[6]

Physicians currently in practice in the United States may not recognize the symptoms of poliomyelitis or of vaccine-induced neurologic complications. The annual number of reported cases of poliomyelitis fell to fewer than 0.1 per 100,000 after 1965.[7] Inasmuch as more than 50% of physicians in practice in the United States completed training after 1965, many have not seen a patient with poliomyelitis.[8] If the diagnosis is considered, laboratory confirmation may be difficult for many practicing physicians. At the time of paralysis, antibody titers have often already peaked and a significant change in titer is no longer demonstrable. One or more strains of vaccine poliovirus may be excreted in the stool for several months after immunization. Because infection with other enteroviruses, and perhaps *M. pneumoniae*, may cause paralytic disease, culture and serologic tests for these pathogens should be performed to exclude these causes. Grist and Bell[9] reported that serologic confirmation of poliovirus infection in Scotland was most often requested by orthopedic surgeons or neurologists attending to late complications. Moreover, the facilities for viral cultures are not easily available to physicians in small community hospitals. Vaccine-related poliovirus infection may not have been considered in patient 3 if viral cultures had not been done. Although the association of complications with vaccine administration can usually be made with reasonable certainty by temporal association, physicians may be reluctant to do so without laboratory confirmation.

The current method of surveillance in the United States, that is, passive reporting of cases, may underestimate the frequency of vaccine-related complications. In other countries, active surveillance has been shown to discover cases more efficiently.[10] Finally, physicians may be hesitant to associate paralysis with the vaccine or to report vaccine-associated complications for fear of potential liability. Because major sequelae appear to affect the legs in most instances, surveillance directed at patients attending rehabilitation centers, brace shops, crippled children services, and specialists in neurology and orthopedic surgery might yield a higher incidence of vaccine-associated paralytic poliomyelitis. Perhaps the advisability of concomitant administration of DTP with OPV should be examined, or alternative vaccine regimens explored.

REFERENCES

1. Moore M. Poliomyelitis in the United States, 1969-1981. J Infect Dis 1982;146:558.
2. van Wezel AL, Hazendonk AG. Intratypic serodifferentiation of poliomyelitis virus strains by strain-specific antisera. Intervirology 1979;11:2.
3. Hill AB, Knowelden J. Inoculation and poliomyelitis. Br Med J 1950;2:1.
4. Davis LE, Bodran D, Price D, et al. Chronic progressive

99th Congress
2d Session

COMMITTEE PRINT

COMMITTEE PRINT 99-LL

CHILDHOOD IMMUNIZATIONS

A REPORT

PREPARED BY THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 1986

U.S. GOVERNMENT PRINTING OFFICE

63-658 O

WASHINGTON : 1986

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

IV. SURVEY OF VACCINE MANUFACTURERS

A. Introduction and Methods

The shortage in the supply of DTP vaccine in early 1985 raised questions regarding the dependability of the supply of vaccines in the United States. Testimony by commercial vaccine manufacturers at the time the shortage became apparent in December 1984 suggested that certain characteristics of the vaccine market, particularly the potential for costly liability suits against vaccine manufacturers and the limited size of the market for vaccines, are threatening the reliability of vaccine supply. There are currently only a few institutions involved in the production and distribution of vaccines. There is only a single supplier of some products. Some believe that the potential of large awards in suits alleging vaccine related injuries has increased the cost of manufacturers' liability insurance. In at least one instance, a manufacturer was forced temporarily to withdraw its products from the market when liability insurance become unavailable.

In light of this situation, the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce decided to survey producers of childhood vaccine products to obtain more detailed information. During the spring of 1985, the staff of the Subcommittee developed a questionnaire for this survey. The questionnaire focused on five major issues related to the production and distribution of childhood vaccines: 1) vaccine compensation litigation and claims; 2) the cost of product liability insurance for vaccine manufacturers; 3) reseach and development activities; 4) vaccine pricing and sales information; and 5) stockpiles and inventories of vaccines. Information in these areas was requested for the time period from January 1980 through March 1985. The questionnaire was mailed to the five commercial manufacturers and distributors of vaccines used in childhood immunization programs (MMR, DTP, polio and Haemophilus influenzae vaccines) and to the two State organizations involved in the production and distribution of vaccines. These seven organizations completed the questionnaires and returned them to the Subcommittee.

B. Summary of Findings

1. Litigation

During the study period (January 1980 through March 1985), there were 299 suits filed against the producers of childhood vaccines seeking compensation for injuries alleged to be due to vaccines.

Nearly 60 percent of these cases were for injuries related to DTP vaccines. Most of the 299 suits (84 percent) were for injuries related to childhood vaccines. Over the same 63-month interval, 83 claims were filed with the vaccine producers that did not result in litigation. Table 9 shows the number of suits filed by year. The rate at which these suits have been filed has increased every year since 1980.

Table 9. Number of Vaccine Injury Lawsuits Filed by Year, 1980-1985

Year	Number of suits
1980	24
1981	29
1982	39
1983	70
1984	101
1st Qtr. 1985	36
1985 (est.)	144
63-Month total	299

Damages claimed in the vaccine injury suits fall into two catagories, compensatory and punitive damages. For the 299 suits filed during the study period, requests for damages amounted to $3.5 billion, $2.52 billion for compensatory damages and $960 million for punitive damages. However, many of these suits (about 40 percent) did not specify an exact amount of damages but only requested damages in excess of nominal or jurisdictional amounts (minimum damages required for filing suit; this amount may vary from jurisdiction to jurisdiction). Given that many of these suits have not requested a specific level of damages suggests that the claims against vaccine manufacturers are more than the $3.5 billion in damages already specified.

Some of the survey respondents provided case by case information on requests for damages. Assuming similar patterns of requests for damages for all respondents, the data suggest that nearly half of the currently specified damages are requested by a relatively small proportion of the suits. There are an estimated 30 suits (10 percent) requesting damages in excess of $25 million each. These cases account for an estimated $1.7 billion (48 percent) of the total specified prayers for damages. Seven suits ask for damages in excess of $100 million each.

The questionnaire asked for information on the resolution of vaccine injury cases. However, it should be noted that product liability cases typically require several years before they are either settled or tried in court. Thus, the following information on the resolution

of vaccine injury cases filed between January 1980 and March 1985 must be considered incomplete, although it is the best information available at this time.

Of the 299 cases filed between January 1980 and March 1985, 52 cases have been settled (17 percent), 27 cases have been dismissed on motion (9 percent), and three cases have been tried in court (about 1 percent). The remaining 216 cases (72 percent) were still pending as of March 1985.

The survey respondents paid out a total of $16.2 million in settlement payments for the 52 cases that had been settled. As noted by some of the respondents, this figure does not include settlements paid during the 63-month study period on cases filed prior to January 1980.

Three of the 299 cases had been tried by March 1985. In addition, the respondents indicated that six additional cases, filed before the study period, had been tried between January 1980 and March 1985, and one of the 285 cases was tried after the close of the study period in May 1985. Of the ten total cases tried, four resulted in verdicts for the defense (three affirmed on appeal, one appeal is still pending) and six found for the plaintiffs (one subsequently settled for a lesser amount, five appeals are still pending). If the five pending verdicts are upheld on appeal, the vaccine manufacturers will have to pay a total of $17.7 million in damages to plaintiffs. It should be noted, however, that more than half of this amount ($10 million) results from a single verdict. Only this last verdict (recently overturned) detailed the award by type of damages: $2 million in compensatory and $8 million in punitive damages.

The questionnaire requested data on the annual defense costs of vaccine injury litigation that was not reimbursed by insurance. The respondents spent $4.7 million on litigation in 1983 and $9.8 million in 1984.

2. Liability Insurance

The survey included several questions related to the liability insurance coverage of the vaccine producers. Because the liability coverage arrangements of the two State owned producers differ from the arrangements of the five commercial producers, the responses to these questions are presented separately for the State producers.

The liability of two State organizations producing and distributing vaccines is insured by the respective State governments. Both States are self-insured and must pay any awards themselves. In one State, the State's liability for damages is limited by statute to $100,000 per claim.

All five commercial producers had insurance coverage of their liability for vaccine injury lawsuits under umbrella policies that

also covered the liability of their parent corporations for all other products manufactured and distributed. Therefore, it is difficult to separate the cost and coverage of insurance for liability related to vaccine injuries from the cost and coverage of liability insurance for other products. Also, changes in a parent corporation's premium or coverage may be related to liability for products other than vaccines.

The five commercial producers were covered by umbrella policies held by their parent corporations with total annual aggregate and per occurance liability limits of about $1.3 billion dollars in 1985. Between 1984 and 1985, two firms increased their liability limits, one firm's limits stayed the same, and one firm's limits were reduced. The fifth firm lost its liability for DTP vaccines except for contracts existing as of June 1984 and was not able to renegotiate a new insurance contract until April 1985. The policy limits of all the policies in effect in 1984 applied to both defense and indemnity costs. This changed somewhat in 1985 when one firm's policy limits excluded defense costs for DTP vaccine injury cases.

All five commercial firms are self-insured to some extent and retain funds each year to cover any self-insured expenses. In 1985, the total self-insurance retentions of these five firms was $41 million. This amount represents an increase of 39 percent over the $29.5 million in self-insurance retentions in 1984. It should be noted that this level of retention is intended to cover the self-insured liability for all products of the parent corporations, not just for vaccine related liability expenses.

The liability insurance policies for all of the commercial respondents contained special provisions relating to coverage of vaccine products. Coverage for swine flu vaccine was excluded from all policies. However, it should be noted that under the Swine Flu Act (P.L. 94-380), manufacturers were generally relieved of their liability for injuries resulting from the administration of the swine flu vaccine, with the liability for such claims being transferred to the Federal Government. Beginning in 1985, two manufacturers' insurance policies impose a $250,000 deductible for claims related to certain vaccines, subject to specified annual limits. One manufacturer's policy excludes from coverage the cost of legal defense for cases related to certain vaccines. Under this policy, the manufacturer will have to pay any costs of defending itself. The liability insurance policies are generally cancellable with 90 days notice.

In 1984, the parent companies of the five commercial vaccine manufacturers surveyed paid $10.2 million in liability insurance premiums. This amount is slightly less than the $10.7 million in premiums that was paid in 1980. However, it should be noted that premium data for 1985 submitted by two respondents suggests that their liability insurance premiums would be somewhat higher in 1985 than they were in 1980, representing a large one year increase between 1984 and 1985. All five respondents indicated that they expected their liability premiums to increase substantially in the near future (estimates ranging from 50 to 300 percent) for coverage with liability

73-717 O - 88 - 4

limits that are 50 or more percent lower than current limits. None of the companies obtain their insurance policies through competitive bidding. According to one respondent, "the issue is availability at any price." One of the State producers once sought competitive bids for liability coverage of vaccines distributed outside its borders, but did not accept any of the bids after it realized that the revenues from out-of-state sales would not even cover the bid premiums.

In 1980, the total product liability insurance premiums of the parent companies of the five commercial respondents were approximately 0.086 percent of annual gross sales, premiums of $10.7 million on sales of $12.5 billion. By 1984, these premiums had declined to 0.063 percent of gross sales. During this period, gross sales increased faster than liability insurance premiums for four of the five respondents.

Finally, the questionnaire asked for information regarding losses and payments that were paid by these firms' liability insurers for vaccine related claims and suits. For four of five respondents, the annual losses and expenses from 1980 through 1984 were less than their self-insurance retention amounts. That is, the insurers for these four companies did not pay out any losses. For the fifth firm, the insurer paid out approximately $700,000 in settlement costs.

3. Research

All seven survey respondents (including the two State organizations) conduct programs of research and development for new and safer vaccines. Some of these research efforts are now in the clinical trials stage of development. The descriptions of these research and development efforts were generally vague due to the confidential nature of these activities in a commercial environment. However, it appears that some efforts are being made to develop new vaccines. Also, some of the current research efforts are being directed toward the improvement of existing products, including improved childhood vaccines.

In general, it appears that the research and development of vaccines conducted by the commercial manufacturers is financed by the individual corporations. Only one firm is currently receiving Federal funds for support of a clinical trial of a new vaccine. A second company stated that it had received $400,000 in Federal support for vaccine research and development between 1981 and 1985. A third stated only that it had received some Federal support "at one time." Two firms stated that they had never received any Federal support for vaccine research and development.

Both State producers are also engaged in vaccine research and development with combined expenditures of $535,000 per year. Of this amount, 56 percent comes from State funds, 30 percent comes from Federal funds, and the remaining 14 percent from private philanthropic organizations.

The seven respondents currently hold 27 patents and product licenses for vaccines and vaccine production. Some of these are exclusively held.

4. Vaccine Prices and Sales

Vaccines are commercially sold in three "markets:" sales to the Federal Government (including sales through the CDC's consolidated contract purchases made on behalf of State and local governments); bulk sales to State and local governments and other large purchasers; and retail sales to physicians, clinics and hospitals. The prices charged for vaccines in each of these "markets" vary, due in part to the stronger negotiating positions of large purchasers. The ratios of prices paid in these markets vary both by vaccine and by vaccine manufacturer. Based on responses to the survey, the data suggest that vaccine prices in the bulk sales market are 0 to 50 percent higher than prices paid by the Federal Government. Retail vaccine prices range from 50 to 300 percent higher than the prices paid in the Federal market.

The two State producers do not participate in any of the commercial markets for their products. Both organizations distribute greater than 95 percent of their products within their respective State borders at no cost. One of these entities has sold some vaccine to neighboring States in response to emergency requests. In these cases, the vaccine was sold at market prices and the receiving State was required to assume all liability associated with the vaccines.

Based on the commercial manufacturers' pricing data collected by the survey, the prices of vaccines used in childhood immunization programs increased by between 50 and 900 percent between 1980 and 1984, depending on the vaccine, the manufacturer, and the market. The retail price of DTP vaccine increased by the greatest percentage, with most of that increase occuring since 1983. Prices of other vaccines increased between 50 and 200 percent, with the increases occurring relatively steadily over the 5-year interval.

There were only two instances cited in the survey of sales of vaccines between vaccine manufacturers. The first occurred in 1979 and 1980 when one firm purchased a small amount of DTP vaccine from another. This vaccine was purchased for $1.70 per 15 dose vial and then resold in the retail market to private practitioners at $4.44 per vial. The second sale occurred during the DTP crisis of 1984 and 1985. Based on public testimony by Robert Johnson of Lederle Laboratories, Lederle purchased more than 10 million doses of DTP from Wyeth Laboratories at 20 cents per dose and redistributed it at a price of about $2.80 per dose.

Total sales of vaccines are reported in two ways: gross sales and net sales, where net sales are equal to gross sales less unused

product returned to the manufacturer. Table 10 shows aggregate gross and net sales volume of the survey respondents by type of vaccine for years 1981 through 1984.

Table 10. Gross and Net Sales of Vaccines by Survey Respondents, 1981 - 1984.

Gross sales (in millions)

Year	Childhood vaccines (DTP, MMR and polio)	Other vaccines	Total
1981	$ 68.7	$47.2	$115.8
1982	79.7	61.2	140.9
1983	105.1	68.3	173.4
1984	132.3	73.2	205.5

Net sales (in millions)

Year	Childhood vaccines (DTP, MMR and polio)	Other vaccines	Total
1981	$ 64.0	$39.9	$103.9
1982	73.9	52.8	126.7
1983	99.1	57.8	156.9
1984	126.0	64.5	190.5

In 1984, the gross sales of vaccine products by the survey respondents was $205 million. Net sales in 1984 were 93 percent of gross sales, or $190 million. Between 1981 and 1984, gross sales of vaccine products increased by 77.5 percent (from $115 million to $205 million). Net sales increased by 83.3 percent.

In 1984, childhood vaccines (DTP, MMR and polio) accounted for 64.4 percent of gross vaccine sales ($132.3 million) and 66.1 percent of net sales ($126.0 million). Gross sales of childhood vaccines increased by 92.6 percent between 1981 to 1984, accounting for an increase of $63.6 million in sales revenues. This increase in revenues is largely due to increases in the prices of these products since demand for childhood vaccines has remained relatively constant over this period.

In response to a question about the relative profitability of vaccine products as compared to other products, the five commercial

respondants noted that their vaccine product lines were about as profitable as the other products sold by these corporations, but somewhat less profitable than other pharmaceutical products. One respondent qualified its response by noting that "our pediatric vaccines have become more profitable in recent years . . . ." Other respondents noted that the true profitability of their vaccine product lines could not be determined given the potential liability in lawsuits related to these products.

5. Stockpiles and Inventories of Vaccines

Six of seven survey respondents maintain inventories of finished products. In some cases, vaccine inventories are large enough to supply national demand for several months. In addition, three of the respondents maintained stockpiles of vaccine under contract to the CDC, at the time the survey was conducted. Since March 1985, a fourth company has also entered into a contract with CDC to stockpile vaccine.

Chairman RANGEL. Thank you very much.

Mr. Dorgan.

Mr. DORGAN. Mr. Chairman, I would just like to ask Jeff if he might recount for us your apparently personal experience in seeking redress for the injury done to a family member.

Mr. SCHWARTZ. It is a little bit touchy and personal and I would prefer not to go into great detail about my situation other than to say we filed an initial suit at the time and eventually withdrew the suit even though we thought we had a good claim, because of a variety of personal stressful family circumstances. I would be willing to explain our personal situation in private. The more important point is about what the group's experience is. The group's experience is that our parents have had no alternative but to go to court. So parents who are faced with lifetime care for their children, long after the parents are gone, how are they going to pay for that? They have no choice but to sue and in many instances those suits have been brought.

Now, I think Mr. Waxman did inadvertantly leave one misleading impression. There is a good report done by his staff that says there are a few cases that have been won, a few cases that have been lost; there are a large number of cases that have been settled, et cetera, but the point is so far the awards and settlements are not that big, not as big as the administration and vaccine makers would lead you to believe. We urge you to look at the Health Subcommittee's staff report.[1] The point is some parents have said if they had a choice they would go to a no-fault compensation system. If parents knew it was going to be fair, if they knew it was going to be quick and if they knew it could take care of their children, many parents would be willing to sacrifice the potential for a big score to get their children taken care of.

Mr. DORGAN. I didn't mean to leave the impression I wanted to walk you through a personal discussion about your circumstance. I was trying to understand the typical circumstances some find themselves in when they have this sort of injury. My guess is that each family is left pretty much to fend for itself. Do you get a lawyer? How did you go through the time-consuming task of litigation and face an uncertain outcome at the end?

I guess I wanted you to discuss that just generally from your experience.

Mr. SCHWARTZ. I appreciate the question because it is important to understand who these families are prototypically. They involve children who in the long-term problem cases, involve children who have seizure disorders, who are multiple handicapped, who require round-the-clock care, and who have extraordinary expenses of all sorts. In order to sort out all these kinds of problems, parents have to see a number of doctors, therapists, educational specialists, and then lawyers to try to figure out what can be done for these kids. Some of them get good lawyers; some of them get not so good lawyers. Some of them win. Some of them have cases that they have taken to a lawyer but the lawyer has not filed for years. Some of

[1] See report by Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, "Childhood Immunizations," Committee Print 99-LL, 99th Cong., 2d Sess. (Sept. 1986), pp. 85-92.

them have been tried promptly. There is a range of experience and it is frustrating to not be able to be sure that you can provide adequately for your child.

Mr. DORGAN. We talk about kids and children. This is not exclusively kids and children, is it? I know of a case of someone in their 50's who took polio vaccine.

Mr. SCHWARTZ. Contact polio is the situation in which childhood vaccines can transmit impacts to the people who are surrounding them. The law covers those cases, by the way.

The law covers those cases and they well should be covered. But I urge the committee not to assume that we are talking about a one in a million shot. The commonly cited statistics here just really don't bear scrutiny. We can go into greater detail with you and your staff to show you why not, but there is a recent medical journal article that says we have not been looking for the side effects of these vaccines. Once doctors started looking for the side effects of the polio vaccines, they found one in 37,500 cases of severe neurological impact. That is a whole big different magnitude of order than one in 1 million.[2] We think the same is true with respect to these other vaccines. We understand that makes the problem worse from your standpoint but we are trying to be honest with you here and we are trying to get honest recognition of the size of this problem. It is not a minuscule problem.

Mr. DORGAN. It makes it worse especially with respect to the retroactive cap that was placed on the legislation that we passed.

Mr. SCHWARTZ. The retroactive cap works two ways. I honestly believe there are many more kids out there that have been injured or killed by childhood vaccines than that retroactive cap allows for. On the other hand, the ability to document that those injuries vaccine related when they occurred 20 years ago is very difficult because there was not sensitivity then to the dangerous side effects of these vaccines. Doctors weren't recording these reactions. Parents were not sensitized to them years ago. As a practical matter, I think relatively fewer claims for the old cases will be filed than are really justified, because causation will be very difficult to prove with inadequate records.

Mr. DORGAN. Thank you very much.

Mrs. KENNELLY. Your excellent testimony gives us broad latitude. You are more or less saying to us find an answer and we will help you find an answer. I wonder if you would address the present piece of legislation that has been signed, was passed by us and signed. Are there any particular parts that you could say right now, leave those in and go on from there. Are there any parts more important than other parts? We are really thrashing around on this thing.

Mr. SCHWARTZ. Our general message to you is unless you enjoy pain and suffering yourself don't try to revisit the fight that has been going on for 5 years. In terms of our interest we feel most strongly that any restriction on the parents' right to sue to protect their children is a mistake. It is a mistake because that is a right that is necessary to assure adequate care by the manufacturers and

---

[2] See Gaebler, et al., "Neurological Complications in Oral Polio Vaccine Recipients," Journal of Pediatrics (June 1986), pp. 878-881.

doctors. That is a right that is necessary to assure that the compensation system really provides adequately for the children's needs. So we think preservation of that right is important.

There are a few minor things we would like to see changed. We don't understand a compensation system that does not have an effective deadline for decisionmaking. There needs to be an up or down decision within a reasonable time so a parent can say, okay, let's take the award or let's go to court. The compensation process must not drag on for years while the children are left uncared for.

We also feel strongly that the decisionmaking about an individual case, whether that case fits within the table or otherwise deserves compensation, should be made by a politically independent entity. That is why we supported the special master/magistrate concept in the Federal courts. We are very concerned that given HHS's historic hostility and denial of this problem, we are very concerned HHS will find a way not to see any of the cases that are really there if the compensation system is put under their charge.

We want the Federal judiciary that has political independence, using a special master or magistrate system, to expedite compensation decisions.

We try not to be dogmatic. There are a lot of things that could be changed in the context of an acceptable total program, but we strongly urge this subcommittee to focus on the funding questions and leave the other questions that we fought through so difficultly for the last 4 years to the resolution that has already been made by Congress. We did not support all parts of the law. We didn't like all parts of it. But we supported the package as a whole because we knew practically this was the best that could be done.

Mrs. KENNELLY. So the bottom line is you want to leave the avenue of litigation open, at the same time provide a revenue source that is permanent and therefore the individual who has had the very serious problem has a choice?

Mr. SCHWARTZ. An incentive we think under the system to take compensation where compensation is adequate and reliable, but allow the parent to sue when there is a clear demonstration of wrongdoing, or otherwise when the parent is determined to go to court.

When a doctor gives the shot four times even though there has been a serious reaction after the second shot, and the third and fourth shots leave the child permanently brain damaged, we ought not take away the right of the parent to sue that doctor, because that lawsuit not only provides for the child's needs but it sends a message to the rest of the doctors to administer this vaccine properly. The same goes for the drug companies. They should take care to manufacture their product properly and to make it as safe as possible.

Mrs. KENNELLY. Thank you.

Chairman RANGEL. Thank you very much. The committee welcomes the opportunity to work with you as we try to reach a conclusion to this bill. Thank you for the great work you have done.

The next panel is Lederle Laboratories, Bob Johnson, president, from New Jersey, Merck & Co., Mr. MacMaster, president, and Connaught Labs, Mr. Williams, executive vice president.

Gentlemen, we thank you for sharing your interest in this legislation. We welcome your testimony. By unanimous consent your full statements will appear in the record and we will proceed under the 5-minute rule. Mr. Johnson.

STATEMENT OF ROBERT B. JOHNSON, PRESIDENT, LEDERLE LABORATORIES DIVISION, AMERICAN CYANAMID CO., ACCOMPANIED BY RONALD J. CRACAS, COUNSEL

Mr. JOHNSON. Thank you. I would like to comment that I am accompanied today by Ronald J. Cracas of our legal department.

We believe that the committee faces a very difficult task to fund this National Childhood Vaccine Injury Act. It is a well-intentioned but we believe a seriously flawed effort. As we are a manufacturer of two of the three vaccines that are covered by the act we obviously have a very special interest. The Energy and Commerce Committee indicated that the 1986 act was designed to serve two purposes: first, to offer compensation for those unfortunate few injured in the course of the Nation's Childhood Vaccination Program; and, secondly to control the cost to the Nation's vaccine programs by providing predictability to vaccine manufacturers faced with an unprecedented onslaught of product liability litigation. This unpredictability has led to a dramatic increase in vaccine prices and has threatened the continuity of supply.

We believe that the 1986 act fails to achieve its objective of containing costs. In fact, it probably will significantly increase the cost of vaccines. The 1986 act creates a new entitlement program which is likely to be far more expensive than anything predicted last year. It will therefore result in heavy new taxes on users of vaccines. Under the law the criteria for awarding compensation are so vague and open ended that large numbers of unmeritorious cases may actually receive compensation.

Secondly, minor injuries are eligible for compensation if medical bills exceed $1,000. Such a system is likely to attract a large number of nuisance claims which will be expensive to process.

Third, substantial attorneys fees can be awarded whether or not the claimant is successful and this will attract more claims and raise the cost of the program. Virtually unlimited retroactivity opens the system to a vast number of old claims which because of their age will be difficult or impossible to refute.

Last, the long-term liabilities imposed on the fund cannot be predicted because any award can be reopened at any time. In this context, a kind of an adverse selection might well occur, cases that would never result in compensation awards under prior law would collect large sums from the Federal fund while significant cases that expose manufactures to large potential liabilities would remain in the tort system. Also there may be additional costs for separate suits brought against physicians who may not be protected by the new law.

At present we include $8 per dose in our price for DTP vaccine—the vaccine for diphtheria, tetanus, and pertussis—to provide for future liability costs. The law makes no significant change in the rules of the tort law that would justify a reduction of this charge. We believe those cases in which claimants accept compensation

from the Government fund are likely to be the weaker ones. Lawyers will advise claimants with good cases to go to court to escape the award limitations in the administrative system. The manufacturer will still be faced with the cases in which sympathetic juries can award large sums.

How many claims will be filed in the administrative system? No one knows but our experience under the tort system suggests the number of claims will mushroom. Emotional publicity about injuries attributed to DTP vaccine coupled with the emergence of a network of plaintiffs lawyers advertising for clients has led to a sharp increase in the number of suits filed against us from 1 in 1981 to 29 in 1984 to 110 in 1986. Since the act provides for virtually unlimited retroactivity and since the lawyers will be paid out of the Government fund, we would expect a flood of claims both old and new. As a result, we would have to continue most if not all of the $8 liability charge built into our price. Whatever the tax on the DPT vaccine turns out to be, whether it's $4, $8, or $12, or even more, that amount will be added to the price parents and the government must pay for this essential vaccine. This impact will fall heavily on the public health programs which currently purchase about 45 percent of the doses of childhood vaccines sold in this country. The impact on the Treasury might be worse if higher prices or physician liability drive more children into public vaccination programs.

A number of major revisions need to be made in the act. Let me stress three of these.

First, the liability provisions of the 1986 act should be amended to assure that manufacturers will not be found liable in the tort system if they have fully complied with applicable government regulations. Second, the rules which permit claimants to reject administrative compensation and file tort suits needs to be tightened. Third, provisions should be deleted which may have the effect of preempting innovative State vaccine compensation programs like those recently enacted in North Carolina.

Finally, any tax should be at a uniform predetermined level for each of type of vaccine. One type of vaccine should not be asked to subsidize the liability costs of another. Attempts to apportion compensation costs among manufacturers and to establish a different tax for each company are doomed to failure. There is no sensible and rational way to allocate the costs of a compensation system other than by a flat tax on each unit sold.

Allocation is particularly difficult because the system covers claims on products of manufacturers who are no longer in the business or cannot be identified and because it covers claims on products of new entrants who have not contributed to the fund.

Thank you sir.

[The prepared statement follows:]

Testimony Concerning Funding
Of the National Childhood Vaccine Injury
Compensation Program
By Robert B. Johnson
President
Lederle Laboratories Division, American Cyanamid Company

Mr. Chairman and members of the Subcommittee:

The passage of the National Childhood Vaccine Injury Act of 1986, as recommended by the House Energy and Commerce Committee, has left this Subcommittee with an exceedingly difficult task. In our view, the 1986 Act represents a well-intentioned, but seriously flawed, effort to deal with a very complex problem. I hope today to offer a few observations from the vantage point of my company, Lederle Laboratories, a major manufacturer of two of the three vaccines covered by the new law.

The Energy and Commerce Committee indicated that the 1986 Act was designed to serve two purposes. First, it was intended to offer compensation for those unfortunate few who, through no fault of anyone, incur injuries in the course of the nation's childhood vaccination programs.

Second, it was intended to help control the cost of the nation's vaccine programs by providing predictability to vaccine manufacturers faced with an unprecedented onslaught of product liability litigation. This unpredictability has led to dramatic increases in vaccine prices and has threatened the continuity of supply. It also discourages research and development of new and improved vaccines.

We believe that the 1986 Act fails to achieve its objective of containing costs. In fact, it will probably significantly increase the cost of vaccines. The reasons for this failure are identifiable and should be corrected before any effort is made to provide funding.

Let me first explain how we conclude that the Act will increase vaccine costs, a very large proportion of which fall directly on the federal government. I will then identify three of the items most in need of revision.

The 1986 Act creates a new entitlement program which is likely to be far more expensive than anything predicted last year. It will therefore result in heavy new taxes on users of vaccines. Under the law:

1. The criteria for awarding compensation are so vague and open-ended that large numbers of unmeritorious cases may actually receive compensation.

2. Minor injuries are eligible for compensation (if medical bills exceed $1,000). Such a system is likely to attract a large number of "nuisance" claims which will be expensive to process.

3. Substantial attorneys fees can be awarded whether or not a claimant is successful. This will attract more claims and raise the cost of the program.

4. Virtually unlimited retroactivity opens the system to a vast number of old claims that, because of their age, will be difficult or impossible to refute.

5. The long-term liabilities imposed on the fund cannot be predicted because any award can be reopened at any time.

In this context, a kind of adverse selection might well occur: cases that would never result in compensation awards

under prior law would collect large sums from the federal fund, while the significant cases that expose manufacturers to large potential liabilities would remain in the tort system. There also may be additional costs for separate suits brought against physicians, who may not be protected by the new law. For these reasons, this Subcommittee cannot assume that every dollar of tax it imposes on users of vaccines would be offset by a dollar reduction in vaccine prices. Because the Act places no significant limitations on tort suits, my company's liability costs would not change appreciably.

At present we include $8.00 per dose in our price for DTP vaccine -- the vaccine for diptheria, tetanus, and pertussis -- to provide for future product liability costs. Those costs might go down if the new law provided any reasonable limitations on a claimant's recovery. But the law makes no significant changes in the rules of tort law that led me to establish the $8.00 charge.

First, although the law reduces the possibility of unjustified punitive damage awards, this change will probably have little impact on vaccine prices. The likelihood of punitive damages was so unpredictable and unquantifiable that it was not a signficant factor in the $8.00 per dose liability charge. In any event, juries inclined to award huge amounts to sympathetic plaintiffs can base their awards on other categories of damages, such as lost wages or pain and suffering.

The Act also states that a warning is presumed to be adequate if it complies with certain governmental standards. But even this obviously sensible provision is of limited help since it is made inapplicable in all cases where the plaintiff can convince a jury that the manufacturer was negligent in failing to add something else to his warning. With this limitation, the new provision does not significantly change existing law.

With regard to claims alleging that a vaccine's "design" is defective, presumably because of the claim that a "safer" vaccine was possible, the law provides no new defense at all. In fact, one federal judge in Utah has recently read the new law in a way that confirms plaintiffs' right to maintain tort suits based on design defect claims. While we disagree with this judge's interpretation of the Act, it is rapidly becoming clear that the new law will not be of any significant help to manufacturers in coping with the litigation they face. For those cases going into the tort system, we would expect no significant reduction in liability exposure if the new law were to go into effect.

We believe those cases in which claimants accept compensation from the government fund are likely to be the weaker ones. Lawyers will advise plaintiffs with good cases to go to court to escape the award limitations in the administrative system. The manufacturer will still be faced with the cases in which sympathetic juries will award large sums.

Now, let us consider how many claims will be filed in the administrative system. No one knows how many, but our experience under the tort system suggests that the number of claims will mushroom. Emotional publicity about injuries attributed to DTP vaccine, coupled with the emergence of a network of plaintiffs' lawyers advertising for clients, has led to a sharp increase in the number of suits filed against us -- from one in 1981, to 29 in 1984, to 110 in 1986. Since the Act provides for virtually unlimited retroactivity, and since the lawyers will be paid out of the government fund, we would expect a flood of claims, both old and new.

The government will need to impose a substantial tax to cover liability stemming from the large number of claims it will

face. We believe that a charge per dose much larger than the level contemplated by the Energy and Commerce Committee will be needed to handle the flood of DTP claims against the fund. On the other hand, we will have to continue most, if not all, of the $8.00 liability charge built into our price.

For this reason, whatever the tax on DTP vaccine turns out to be -- whether $4.00, $8.00, $12.00 or even more -- that amount will simply be added to the price that parents and the government must pay for this essential vaccine. The impact will fall heavily on public health programs which purchase 45% of the doses of childhood vaccines sold in this country. The impact on the Treasury might even be worse if higher prices drive more children into public vaccination programs.

A number of major revisions need to be made in the Act to correct these problems and permit meaningful reductions in liability costs, and hence, in the total cost of the compensation and tort systems. Let me stress three changes in particular:

First, the liability provisions of the 1986 Act should be amended to assure that manufacturers will not be found liable in the tort system if they have fully complied with applicable government regulations. In particular, manufacturers should not face liability under a "design defect" theory in cases where plaintiffs challenge the decisions of public health authorities and federal regulators that the licensed vaccines are the best available way to protect children from deadly diseases. The Act, although not yet implemented, has already been cited by one court as evidence that Congress intended to authorize tort suits against manufacturers to second-guess the licensing of vaccines by the Food and Drug Administration. We firmly believe that this is exactly the opposite of what Congress intended.

Second, the rules which permit claimants to reject administrative compensation and file tort suits need to be tightened. One possibility would be to make the compensation program the exclusive remedy for all true "no-fault" cases. The law could require a federal official to find that a manufacturer had violated applicable government standards or engaged in fraud or the intentional and wrongful withholding of information before a claimant could proceed from the compensation system into the tort system.

Third, provisions should be deleted which may have the effect of preempting innovative state vaccine compensation programs like those recently enacted in North Carolina. Such programs offer real promise for reducing costs far beyond anything possible under the federal law.

With regard to the compensation system, in addition to the items previously mentioned, we think the Subcommittee should carefully consider:

-- Taking the compensation system out of the federal courts and putting it into a less costly administrative forum where there would be a greater potential for obtaining consistent findings on difficult questions of causation, and where there is at least some possibility that award levels could be kept under control.

-- Benefit levels, the extent of retroactivity, and criteria establishing eligibility for the compensation system should all be carefully reviewed to minimize the risk of a "runaway" compensation system.

-- The Subcommittee should look closely at possible amendments that would require potential liabilities to be fully funded when awards are made, rather than looking to uncertain sources of revenue in future years when unknown levels of required periodic payments might actually become due.

A number of other changes should also be considered, including revision of the "insolvency" and subrogation provisions contained in the Act. The current language in these areas increases, rather than decreases, the uncertainty which is the major cause of high vaccine prices.

Finally, any tax should be at a uniform, pre-determined level for each type of vaccine. One type of vaccine should not be asked to subsidize the liability costs of another type. On the other hand, attempts to apportion compensation costs among manufacturers and establish a different tax for each company are doomed to failure. There is no sensible and rational way to allocate the costs of a compensation system other than by a flat tax on each unit sold. Allocation is particularly difficult because the system covers claims on products of manufacturers who are no longer in the business or who cannot be identified and because it covers claims on products of new entrants who have not previously contributed to the fund.

As this discussion indicates, we believe that Congress clearly could have done better last year. We have long supported legislation that would provide timely and fair compensation to the few children who are injured in the immunization program, while limiting liability sufficiently to restore predictability to the vaccine marketplace. Legislation that would have accomplished both purposes without any federal compensation fund or tax was before the Energy and Commerce Committee. Unfortunately, a different approach was selected. That Committee's proposal was endorsed at the end of the last Congress as part of an omnibus health bill without anything approaching a full debate.

I fully understand that this Subcommittee must focus its attention on the fiscal aspects of the vaccine program and that jurisdiction over health policy issues rests in other subcommittees or elsewhere in Congress. But you should not be forced to approach your task while wearing blinders.

The government has a strong fiscal interest in keeping control over spiraling liability costs in the vaccine area. This interest extends beyond the government financed compensation system. If the Subcommittee feels that it cannot deal with certain features of the law that govern tort actions against manufacturers, it should refer the matter to the appropriate subcommittees before taking action on a tax bill.

I thank you for the opportunity to share my company's views with you. We stand ready to work with the Subcommittee and Committee staff to help develop substantive proposals dealing with all of the issues I have discussed.

Chairman RANGEL. Thank you. Mr. MacMaster.

STATEMENT OF DOUGLAS MacMASTER, PRESIDENT, MERCK SHARP & DOHME DIVISION, MERCK & CO., INC.

Mr. MACMASTER. Mr. Chairman and members of the subcommittee, my name is Douglas MacMaster. I am president of Merck Sharp & Dohme, a division of Merck & Co., Inc. Thank you for the opportunity to testify on this critical topic. Merck appreciates the committee's willingness to examine the issue of funding a vaccine compensation plan we believe will maintain our nation's childhood immunization programs and insure the supply and development of vaccines for these programs.

Merck has had a long standing commitment to preventative health care, particularly the development and use of vaccines. Indeed Merck is the largest nongovernmental investor in vaccine research in the United States. During the last four decades our company has been fortunate to have participated in the development of vaccines to prevent life threatening and debilitating diseases such as measles, mumps, rubella, meningitis, pneumococal pneumonia, and hepatitis B.

Injuries caused by vaccines raise special ethical and social questions.

Society as a whole benefits when an individual citizen agrees to be immunized against a communicable disease. If that individual suffers unavoidable injury, payment of reasonable compensation is a public responsibility. The law should neither be left with the injured individual nor imposed through artificial standards of fault on a manufacturer or physician who has exercised all possible care. Let me emphasize that we have never ought to be relieved of responsibility for making vaccines as pure, potent and safe as existing technology permits. When we have fulfilled that responsibility and unavoidable injuries result, some system other than tort litigation should be available to compensate injured children. Many injured children cannot be compensated today because their injuries were not the result of fault on the part of manufacturers or physicians. The injured were in most cases healthy infants who received vaccines because they were required to do so by State laws designed to protect society as a whole. It is unfair to require these children and their families to bear the cost of catastrophic injuries. The proposed tax to fund this program is a small price to pay for what we as a society stand to gain.

Our involvement with vaccine compensation legislation began in 1975 with discussions of the vaccine liability problem with the Public Health Service, the American Academy of Pediatrics, and other vaccine manufacturers.

Our initial proposals as early as 1977 were for a system which would establish a compensation scheme as exclusive remedy for vaccine injuries with a provision that a manufacturer could be sued by the compensation fund for negligent behavior. Political realities caused us to abandon the exclusive remedy idea and instead to pursue legislation which would permit a claimant to pursue a tort remedy but make compliance with the requirements of the Federal Food, Drug, and Cosmetic Act a complete defense to liabil-

ity. Even this concept had to be abandoned. After a long and difficult 12 years during which we explored numerous alternatives we acknowledge that the compensation law enacted last year is not the original law we envisioned. It is not the law we would have written had there been no other parties involved. Indeed this is by no means an ideal law from anyone's standpoint. However it is a workable compromise. We would have preferred a stronger bill on the liability issues. However this goal was not achievable. We urge the liability issue now be set aside and all parties work toward a fiscally and financially sound funding mechanism so this worthwhile program can begin. We do so because we believe it is a matter of urgent public policy to address problems that continue to beset our Nation's childhood immunization program. The national vaccine injury compensation program can provide both adequate compensation for children and a measure of certainty that litigation based on theories other than negligence will not create an increaseingly unstable climate for manufacturers of vaccines.

We are hopeful that this increased certainty and stability will encourage present manufacturers to continue to produce needed vaccines and others to enter or reenter the field of vaccine research and manufacture. In order for this compensation system to provide improved stability, it must be funded through a mechanism that will provide adequate moneys to pay claims from injured parties and insure funds are available when needed. It must not be a system dependent on an expectation of large continuing appropriations from the Federal Government. We have examined this issue for a number of years and have concluded that a trust fund financed through the imposition of a surcharge or an excise tax on pediatric vaccines could be made fiscally sound. This legislation is in the public interest and is a fair and workable compromise. We have examined many other alternatives and believe this is the best legislation that can be achieved. We urge the subcommittee to focus on the matter of funding and not reopen the debate on liability. We would like to work with you and your staff to enact a funding mechanism which satisfies the needs of injured children but does not unduly burden the childhood immunization program or the Federal Government.

I would also like to compliment the committee for getting so early to this in the congressional year and I hope you can move forward with it successfully.

[The prepared statement follows:]

TESTIMONY OF

DOUGLAS MACMASTER

PRESIDENT, MERCK SHARP & DOHME DIVISION

MERCK & CO., INC.

Mr. Chairman and members of the Subcommittee:

My name is Douglas MacMaster. I am President of Merck Sharp & Dohme Division of Merck & Co., Inc. I want to thank you for the opportunity to testify today on a critical topic of mutual concern.

Merck appreciates the Committee's willingness to examine the issue of funding a vaccine compensation plan that we believe will help maintain our nation's childhood immunization programs and ensure the supply and development of vaccines for these programs.

Merck has had a long-standing commitment to preventive health care, particularly the development and use of vaccines. During the last four decades, our Company has been fortunate to have participated in the development of vaccines to prevent life-threatening and debilitating diseases, such as measles, mumps, rubella, meningitis, pneumococcal pneumonia and hepatitis B. Just a month ago, our new form of hepatitis B vaccine, the first to be made with recombinant DNA technology, was introduced in the U.S. Varivax, a vaccine against the last major infectious viral disease of childhood -- chickenpox -- continues in the process of regulatory review. In addition, supported by the largest private investment in vaccine research in the U.S., scientists in our laboratories continue to work on vaccines against a wide range of diseases, including hepatitis A and herpes simplex 1 and 2, and most recently AIDS.

Compensating Children Injured by Mandated Childhood Vaccines is Sound Public Policy

The favorable cost-benefit ratio of immunization to society as a whole has been well documented. As an example, the CDC cost-benefit analysis of immunization for measles, mumps and rubella indicated that in 1983, 6,885,482 cases of these diseases did not occur that would have occurred without the vaccine. Fully 99.4% of the persons who might have suffered

the adverse effects of the disease were spared. For measles-related deaths alone, the number was reduced to zero in 1983 from the 366 that would have been anticipated without the vaccine.

The CDC report further indicated that the costs of these diseases would have been almost $1.4 billion without a vaccination program. The cost-benefit ratio for the MMR immunization program was approximately 1:14. The long term cumulative impact of such vaccine savings -- preventing human suffering and saving health care dollars -- is enormous.

Unfortunately, in the last ten years, many pharmaceutical companies have abandoned the vaccine business, in part because of liability and insurance supply problems. Only three manufacturers now supply childhood vaccines. For polio and measles-mumps-rubella vaccines, only one company remains in the business; for the other (diphtheria-pertussis-tetanus, or DPT) vaccine, two companies remain. Because of the long lead time required for a new company to begin producing a vaccine, if even one of the remaining companies were to cease doing business, serious problemscould result and the nation might not be able to vaccinate a significant number of eligible children.

The complexity of research and the time required for vaccine development make the cost of investment high. For example, we began our research on a vaccine against chickenpox in 1962 and we still do not have a product available. In addition, vaccine products suffer from self-extinction. There is no repeat business in a life-time vaccine. Thus, the more successful a product is initially, the greater the extent to which its market will disappear over time or be renewable only on increases in the population.

The high costs have been compounded by the uncertain liability risk associated with vaccines. Although most vaccines are extraordinarily safe, they can be associated with adverse reactions in a small percentage of the people who use them. Most of these reactions are minor and self-limiting; but some very rare reactions can be harmful, even fatal. The government can apply the most rigorous standards in approving new vaccines and in testing individual batches of vaccines before they are released. Public health officials can carefully assess the need for

immunization programs, and limit those programs to the segments of thepopulation that are essential to the successful control of communicable disease. Physicians and nurses can administer vaccines with the greatest care. And yet, despite the great care exercised by all these persons, some injuries can still occur.

Even though no one is at fault, courts and juries have understandably sought to compensate injured persons by developing novel theories of law.However, the present tort system is a "lottery" for claimants, manufacturers, health professionals and insurance companies alike. A few injured children receive large jury awards, but many others receive nothing or must wait years to receive any payment. It is the unpredictability of the future under this present system that has been a major disincentive for vaccine innovation in the U.S.

Merck Has Worked on This Issue for Many Years and Explored Numerous Alternatives

Our involvement in the passage of vaccine compensation legislation began in 1975 with discussions of the vaccine liability problem with the Public Health Service, the American Academy of Pediatrics, and other vaccine manufacturers.

In 1976, the liability problems for vaccines were highlighted by manufacturers' inability to get insurance to cover possible liability arising from the proposed swine flu immunization program. More recently, the prospect of a shortage of DPT vaccine again brought the issue to the forefront.

With the prospect that such crises would continue to reoccur, it became clear that it was necessary to seek some long term solution to this problem that would serve the public interest by providing an uninterrupted supply of necessary vaccines.

Many injured children cannot be compensated today, because their injuries were not the result of fault on the part of manufacturers or physicians. The injured persons were in most cases healthy infants who received vaccines because they were required to do so by state laws

designed to protect society as a whole. It is simply unfair to require these children and their families to bear the cost of catastrophic injuries.

Our initial proposals, as early as 1977, were for a system which would establish a compensation scheme as the exclusive remedy for vaccine injuries for all vaccines, with a provision that a manufacturer could be sued by the compensation fund for truly negligent behavior. Political realities caused us to abandon the idea of an exclusive remedy and instead to pursue legislation which would permit a claimant to pursue a tort remedy, but make compliance with the requirements of the Federal Food, Drug and Cosmetic Act a complete defense to liability, and even this concept had to be abandoned.

Political and budget realities also caused us to abandon our belief that funding for a compensation scheme should be provided by the Federal Government, and, in 1982, we had begun to talk about a bill funded by a surcharge on each dose of vaccine.

In 1982, a bill was introduced in the Senate on the subject of liability for injuries from childhood vaccines in response to publicity surrounding injuries from the pertussis component of DPT vaccine. Despite discussions and negotiations stretching over two years, including direct discussions between the Parents Group and the manufacturers, interested parties were unable to reach agreement over key provisions and the Senate Committee ultimately reported a bill with no liability relief for manufacturers and no compensation procedure for injured children.

Beginning in mid-1985, discussions began with the staffs of Representatives Waxman and Madigan. In the summer of 1986, a bipartisan bill was introduced sponsored by Representatives Waxman and Madigan. After hearings in which many parties here today testified, a vaccine compensation package was passed as a part of the omnibus health bill during the last moments of the 99th Congress.

After a long and difficult 12 years, we acknowledge here today that this is not the law we originally envisioned, and it is not the law we would have written had there been no other parties involved. Indeed,

this is by no means an ideal law from anyone's standpoint; however, we continue to believe that it is a fair, acceptable and viable compromise.

As we testified before the Health and Environment Subcommittee of the Energy and Commerce Committee, Merck believes that an adequatecompensation system must satisfy five objectives. First, and most important, the system must ensure that injured children and their parents are fairly compensated, with a minimum of delay, for their actual monetary losses, such as unreimbursable medical expenses, costs of rehabilitation and lost wages. Second, the system must increase the willingness of the public to participate in immunization programs and of physicians and other health care professionals to encourage such participation. Third, it must encourage manufacturers not only to continue providing existing vaccines, but also to devote substantial resources to the discovery and development of new vaccines. Fourth, the compensation system must have the potential to alleviate the liability and insurance crisis that confronts some manufacturers of vaccines. Finally, the system must be fiscally responsible. We believe that the National Vaccine Injury Compensation Program does achieve the first four objectives and by working with you we can develop a funding mechanism to satisfy the fifth objective.

Let me emphasize that we have never sought to be relieved of responsibility for making vaccines as pure, potent, and safe as existing technology permits. When we have fulfilled that responsibility and unavoidable injuries result, we believe that some system other than the tort litigation system should be available to compensate injured persons.

The law establishes a compensation system for children injured by one of the mandated childhood vaccines polio, measles, mumps, rubella, diphtheria, pertussis and tetanus. Claimants must first file a claim under the administrative system and may be given an award if medical evidence shows that an injury was caused by a covered vaccine. A vaccine injury table establishes presumptive causation for the injuries most commonly attributed to the existing vaccines. The claimant may either accept the award and waive the right to sue the manufacturer or may reject the award and sue the manufacturer in the tort system.

The Changes in the Tort System Are Fair and Are the Best Which Were Politically Achievable

The law makes several important changes in the tort system which we believe will lend more certainty and predictability for manufacturers andtheir insurers when a claimant sues. First, in the absence of fraud or intentional wrongdoing, punitive damages may not be awarded against a manufacturer who has complied with FDA standards for testing and labeling. Second, a vaccine manufacturer will not be liable for damages from injuries due to unavoidable side effects if its product was properly prepared and accompanied by proper directions and warnings. Third, a vaccine is presumed to be accompanied by proper directions and warnings if the manufacturer complied in all material respects with the Federal Food, Drug and Cosmetic Act. And fourth, a vaccine manufacturer cannot be held liable solely for failing to provide warnings directly to vaccine recipients, rather than to physicians.

Any Effort to Reopen the Debate on the Liability Issues Threatens the Entire Program

We would have preferred a stronger law on the liability issues, just as we would have preferred a budget which would permit the funding of the compensation scheme from general revenues. We didn't see either of these goals as realistically achievable. Let me give you an example. In 1985, Representative Madigan introduced a separate bill designed to require claimants to approach the manufacture of the vaccine for compensation. That bill would have encouraged claimants and manufacturers to submit to binding no-fault arbitration by medical experts. This proposal, which depended in large part on a one million dollar cap on compensatory awards, was not seriously considered in the House. We urge that the liability issue now be set aside and that all parties work toward a fiscally and financially sound funding mechanism so that this very worthwhile program may begin.

If this law is only a compromise, you must wonder why we continue to support efforts to have this plan put in place. We do so because we believe it is a matter of urgent public policy to address the problems that continue to beset our nation's immunization program.

The National Vaccine Injury Compensation Program Can Provide Both Adequate Compensation for Children and a Measure of Certainty and Predictability for Manufacturers

We believe that the vaccine compensation system can provide both adequate compensation for children and a measure of certainty that litigation based on theories other than negligence will not create an increasingly unstable climate for manufacturers of vaccines. We are hopeful that this increased certainty and stability will encourage present manufacturers to continue to produce needed vaccines and for others to enter or re-enter the field of vaccine research and manufacture.

A Trust Fund Financed Through a Surcharge or Excise Tax on Each Dose of the Vaccine Would Create a Stable and Adequate Fund

In order for this compensation system to provide improved stability, it must be funded through a mechanism that will provide adequate monies to pay claims from injured parties and ensure that funds are available when needed. It must not be a system that is dependent on an expectation of large continuing appropriations from the Federal Government to pay compensation claims.

We have examined this issue for a number of years and have concluded that a trust fund with up-front lump-sum payments for claimants would be the most fiscally sound. John Butler of Putnam, Hayes and Bartlett has examined this in detail and has provided you with the benefit of his analysis on an earlier panel. In general, Merck supports the financing of the trust fund through the imposition of a surcharge or an excise tax on pediatric vaccines. We believe this excise tax should be weighted to

reflect the differences in adverse experiences among vaccines. This will help spread the costs of the compensation program and even out year-to-year variations.

The funding of the compensation program in this manner helps meet the important objective of fiscal responsibility by creating a self-sustaining fund which would not be dependent upon the general revenues of the Federal Government and which would be an attractive alternative to the tort system for injured claimants.

Injuries caused by vaccines raise special ethical and social questions. Society as a whole benefits when an individual citizen agrees to be immunized against a communicable disease, and if that individual suffers unavoidable injury, the payment of reasonable compensation is a public responsibility. The loss should neither be left with the injured individual nor imposed, through artificial standards of fault, on a manufacturer or physician who has exercised all possible care. The proposed tax to fund this program is a very small price to pay for what we as a society stand to gain.

We would like to work with you and your staff to enact a funding mechanism which satisfies the needs of the injured children but does not unduly burden the childhood immunization programs or the Federal Government.

Mr. COYNE [presiding]. Thank you very much. Mr. David Williams.

STATEMENT OF DAVID J. WILLIAMS, VICE PRESIDENT AND GENERAL MANAGER, CONNAUGHT LABORATORIES, INC., ACCOMPANIED BY CARL GRECO, GENERAL COUNSEL

Mr. WILLIAMS. Good morning. My name is David Williams and I am the vice president and general manager of Connaught Laboratories, Inc., a manufacturer of vaccines and biologicals located in Pennsylvania. With me on my left is Carl Greco, general counsel for Connaught. Connaught is a relatively small $72 million company. It is also the company that will experience the greatest impact of this program and its funding.

Connaught supplies both DPT and polio vaccines, the two principal products covered by the vaccine injury program. We are currently the largest supplier of DPT vaccine in the United States, the product that is involved in most of the vaccine related litigation. Like this subcommittee and Mr. Waxman's subcommittee, we too have wrestled with the compensation funding issue. We respect the efforts of you and your staff to structure a swift and just system and we recognize the difficulties involved.

Connaught fully supports the principle of vaccine compensation legislation. We believe, however, that there are at least four goals for any funding system beyond that of providing just and fair compensation to the individual. These goals are, first, to contain costs and guarantee a source of supply of vaccines. In addition, the fund must maintain incentives for the development of new vaccines, minimize burdens on government and taxpayers, and finally, and most importantly, impose the greatest burden on those most directly responsible for the products that result in the injury.

In light of these goals we believe the law must be reevaluated and a fresh look taken regarding the funding mechanism. A funding system that we feel meets most of these goals is available. It involves a direct accountability system in which the manufacturer bears the cost of the compensation. The system was embodied in legislation introduced by Representative Madigan in 1985. It meets the goals I referred to and it would eliminate the need for the Ways and Means Committee to be involved.

We understand that the funding alternatives being considered by this subcommittee are a direct appropriation and an excise tax. There has even been some talk about a broad based industry tax. The direct accountability system eliminates the need for all of these options. It also eliminates the question of whether there are adequate funds to satisfy the claims, including the large number of retroactive claims that are provided for under the current structure.

In short, a direct accountability system provides for a fair, efficient and speedy way to compensate the injured without imposing undue financial and administrative burdens. We hope that these comments will be of some value to the subcommittee as they advance toward the same goal that parents, physicians, governments and manufacturers all seek.

We would like to thank you for the opportunity to be here and I would ask that our entire statement be introduced into the record at this time.

Mr. COYNE. Without objection, it is so ordered.

[The prepared statement follows:]

STATEMENT OF DAVID J. WILLIAMS, VICE PRESIDENT AND GENERAL MANAGER, CONNAUGHT LABORATORIES, INC.

Mr. Chairman and Members of the Subcommittee, I am David Williams, vice president and general manager of Connaught Laboratories, Inc., a company that produces vaccines and biologicals in Swiftwater, Pennsylvania. With me is Carl Greco, our corporate counsel. Our company is the American subsidiary of Connaught Laboratories Ltd., of Canada.

We welcome this opportunity to offer our comments on funding for the national childhood vaccine injury program.

Connaught's only business is the manufacture of vaccines. Vaccines against childhood diseases comprise the majority of our products. We produce two of the vaccines to be covered under the vaccine injury program. And we are the major supplier of DTP, the vaccine involved in more than 50 percent of the liability cases filed to date.

Connaught, therefore, is the vaccine manufacturer that will experience the greatest impact of the compensation.

Like everyone else concerned with this issue, Connaught wants to see a system that will help children who have suffered adverse reactions to vaccines. We share the sorrow of their parents and recognize the need to assist them. We know the distress that injuries to children causes the physicians who administer vaccines.

At the same time we are concerned about maintaining a steady supply of vaccine at a reasonable price to the thousands of babies each year who need protection against childhood diseases. Roughly a decade ago, there were eight manufacturers of DTP in the United States. Today, Connaught is one of two remaining manufacturers of this vital product.

In June 1984, Connaught was forced to suspend normal distribution of DTP vaccine for nearly a year. Because of problems in obtaining sufficient commercial liability insurance in the face of a rapidly escalating number of lawsuits, distribution was restricted to a very few contracts. The distribution represented just a fraction of our total production capacity.

Our inability to distribute normally caused a national shortage of DTP vaccine, leaving a large number of American babies at risk for potentially life-threatening diseases. Indeed, the situation was so serious that it became the subject of a hearing on December 19, 1984, before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce.

We recognized then, as now, that it will take two measures to solve the vaccine problem. The first is a federal vaccine injury compensation program. The second is development of a new pertussis vaccine, one that, hopefully, may reduce the number and degree of vaccine-related injuries.

Connaught is currently involved in efforts to develop such a vaccine. However, its introduction is still years away.

In the matter of vaccine injury compensation, we have long endorsed federal legislation to assist injury victims and enable manufacturers to assure a constant supply of vaccine.

We applaud the efforts of Representative Waxman and his Subcommittee in attempting to design a law that will assist those children who have had adverse reactions to vaccines. We recognize the difficult problem this Subcommittee confronts in crafting a funding mechanism that is both fair and efficient.

Connaught did take issue with some aspects of the law passed by the 99th Congress, including the funding mechanism originally proposed and certain other aspects of the bill.

These problems, we felt, offset the many positive elements of the legislation. Therefore, we are grateful for the opportunity to contribute to the discussion today.

The purpose of this hearing is to look at the options, alternatives and policy considerations for a funding mechansim and to gather the information that will be necessary in passing legislation on this issue as soon as humanly possible.

Today, Connaught would like to cover four areas:

I. An overview of the public policy challenges inherent in consideration of a funding mechanism;

II. An overview of Connaught's principles and positions on the funding issue;
III. An assessment of the available alternatives and options;
IV. A discussion of additional major provisions of P.L. 99-660.

I. PUBLIC POLICY CHALLENGES

As Connaught sees it, there are five challenges that must be met in arriving at a just and expeditious method of compensation for injured children:

A. Contain costs of the vaccine to consumers;
B. Minimize the financial burden on government and taxpayers;
C. Impose the greatest burden on those most directly responsible for products that result in injury;
D. Insure fairness of competition between domestic and foreign manufacturers; and
E. Maintain incentives for the development of new vaccines.

We acknowledge the difficulty of reconciling these issues. Mr. Waxman's Subcommittee had begun to wrestle with them before P.L. 99-660 was passed. Now this Subcommittee must deal with them. Connaught stands prepared to assist, to the best of our ability.

Unfortunately, many of these issues revolve around economics. But unless we address them, we cannot insure the creation of a fast, fair system of compensation that works.

II. CONNAUGHT'S PRINCIPLES AND POSITION

We would like to state our positions for the record:

A. Connaught stands behind its products; if anyone is injured as a result of one of our products, he or she should be compensated;
B. We fully support the concept of a federal compensation system, where persons suffering vaccine-related injury will receive financial assistance without having to resort to the costly and time-consuming tort system;
C. Connaught believes that a *Direct Accountability* system—whereby the manufacturer whose product resulted in the injury bears the cost of compensation—is the most equitable, efficient method of funding the compensation program;
D. Connaught strongly supports the mandatory recording and reporting provisions of P.L. 99-660, and urges the imposition of penalties for any and all forms of non-compliance; and
E. Connaught is committed to maintaining a stable supply of vaccine to all American children, at the most reasonable price possible.

Below in our assessment of funding alternatives, we describe two options for a direct accountability system.

III. ASSESSMENT OF ALTERNATIVES AND OPTIONS

There are four ways in which the compensation program could conceivably be funded: (A) provision of a spending entitlement; (B) establishment of an excise tax on specific vaccines; (C) a broad-based pharmaceutical industry tax; (D) a direct accountability system, tied to performance.

A. Provision of spending entitlement

It is our understanding that this mechanism would entail a direct appropriation annually to the Department of Health and Human Services.

There are obvious questions as to how high an appropriation must be to cover claims and where the money will come from.

Mr. Waxman's Subcommittee on Health and the Environment estimated that $40 million would have to be borrowed from general revenues over the first three years of the program.

Subsequently, as published in the report of the full Committee on Energy and Commerce, the Congressional Budget Office estimated the cost of $250 million for the first three years, excluding the cost of interest on the loan. We believe that this is a very conservative estimate; the actual amount may be far greater.

Clearly, direct budgetary costs are substantial. Even worse, they are uncertain.

Each year the appropriation is subject to both the politics of the appropriations process as well as the politics of the authorization process. Thus, the appropriation is technically in jeopardy once a year.

Moreover, it is an open question as to whether funds appropriated will be sufficient to meet demand. Although the reporting requirements in P.L. 99-660 may eventually allow for reasonable projections regarding the number of claims, it will

be many years before there are sufficient data to allow for such empirical study. In the meantime, there is no realistic method for predicting the number of claims that can be anticipated in a given year. The legislation is so broad regarding what is to be included as a vaccine injury, that it is impossible to quantify those cases. As it stands, many cases, which under the present system are not compensable because of lack of a causal relationship between the injury and the vaccine, would be included under the compensation system.

Budgetary constraints are also a major consideration. There are obvious problems in creating a program with uncertain—and potentially unlimited—growth.

In short, a spending entitlement raises concerns, in terms of both adequacy and ultimate cost.

B. Vaccine excise tax

This mechanism would involve the levy of an excise tax on all designated childhood vaccines manufactured, produced or imported into the U.S. Conceivably, this tax would be levied on each dose or each multi-dose vial of vaccine.

Like a spending entitlement, the excise tax proposal raises the issue of adequacy. Will the money raised through taxation be sufficient to meet all claims?

In attempting to answer this question, one must address other, equally vexing issues. How many claims can be expected? Can we estimate the average amount of each claim?

Yet another problem is the lag time between program start-up and the collection of any meaningful amount of tax revenue. How are the large number of claims filed at the outset to be compensated? A one-time appropriation may be required to launch the fund. The only other option is to delay acceptance of claims until there are sufficient monies to begin disbursal.

Administratively, the excise tax system is fraught with difficulty. Where is the requisite expertise located in government, to assess the data necessary in determining the level of taxation that will yield sufficient funds to cover claims? What type of substantiation will be required for these data, as well as for individual claims? What government department or agency will substantiate them? Will the process require the creation of a large—and costly—administrative function?

There is also a question as to how tax will be allocated. Typically, there is a 30-month interval between the occurrence of an adverse reaction and the filing of a claim. It is possible that some manufacturers could have abandoned the market within that period. Possibly, to avoid such a result, any new manufacturers entering the U.S. market should be required to pay 110 to 125 percent of the maximum rate, to insure sufficient funds to meet claims that will be filed two and a half years or more down the road.

No matter how these questions are resolved, the fact remains that the administration of the system will be costly and complex. Computations, reporting and collections are expensive.

There is also the potential problem of unintended or unauthorized use of monies collected for the vaccine trust fund. Trust funds set up for one purpose have a history of being used to meet other goals unforeseen by the legislative fathers.

Another difficulty is the potential for an increase in public spending on immunization administration. Recently, as costs of DTP have risen, significant numbers of consumers have moved from the private physician to the public health system for immunization. This trend, coupled with the burdens of a trust fund, would mean increased costs for government and taxpayers. Indeed, if the cost per dose increases dramatically and if there is a corresponding patient shift to the public health system, an excise tax becomes the equivalent of a retroactive appropriation.

C. U.S. drug industry tax

Under this plan, every U.S. company producing pharmaceuticals or biologicals would be assessed a tax on a gross receipts basis.

While we recognize that such a system would benefit Connaught in the short term, we cannot strongly advocate this approach to funding. If all companies were taxed in equal proportion, Connaught would pay roughly .01 percent of the total, even though our company accounts for fully 70 percent of all the DTP sold in this country. DTP vaccine is involved in the majority of all vaccine injury claims.

To strongly advocate this system would be to contradict our basic principle: we stand behind our products, and we are prepared to compensate anyone injured as a result of their administration.

Finally, this proposal could encourage new competitors, particularly foreign manufacturers, to exploit the opportunity to enter the market, share a minimal amount of the tax burden for a short period of time, then pull out of the market before claims against them can be settled.

D. Direct Accountablity System: Let the manufacturer pay

Connaught maintains that the fairest, most efficient funding mechanism is one in which manufacturers assume responsibility for injuries arising from use of their own products. In fact, Connaught is on record here in saying that we expect to compensate anyone who is injured by our vaccine.

Direct accountability defined

The concept of direct accountability was embodied in legislation introduced by Rep. Edward R. Madigan (R-IL) in 1985. The bill provides claimants with an efficient means of compensation once it is proven before a hearing panel that the injury was, in fact, caused by the administration of vaccine. While all manufacturers of that vaccine are named as respondents, the bill also provides that individual manufacturers can be dismissed as a party if the hearing panel determines that the manufacturer did not participate in the manufacture, distribution, sale or administration of the dose or doses of vaccine alleged to have caused the injury.

The advantages of this proposal are numerous. First, it prevents compensation for injuries unrelated to administration of a vaccine. This helps to control overall program costs and ultimately vaccine prices. Second, it enables the manufacturer to prove by a preponderance of the evidence that it was not part of the process that resulted in the injury, thus retaining individual accountability for respondents. At the same time, it offers claimants a just and expeditious alternative means of receiving compensation when vaccine-related injury has occurred. As with P.L. 99-660, it also retains for the claimant the opportunity to opt out of the system after the award is determined.

In short, if you made the vaccine and that vaccine caused injury, the onus is on you, and the government is not directly involved in any issues of funding.

It is a fair and efficient system. Moreover, it limits administrative burdens and costs.

Alternative to direct accountability

A less desirable, but acceptable, alternative is a system in which manufacturers would pay into a pool based upon their pro rata share of injuries. More specifically, a dollar amount would be tabulated and assessed on each dose sold, according to the overall percentage of injuries from that manufacturer's product in previous years.

The data would be drawn from the comprehensive reporting mechanism already provided for in P.L. 99-660. This is a more equitable and direct way to assign costs than the allocation based on market share set forth in the current legislation.

Let's assume that a manufacturer had developed a new pertussis vaccine. What would happen under a system based on market share? If the new product garnered an increased market share, the manufacturer would find itself paying a greater percentage into the compensation pool, even if the new vaccine proved to result in a lower number of injuries.

While preferring the first approach, Connaught would support either of these direct accountability systems over a funding mechanism based on market share.

A direct accountability system offers maximum benefit to all concerned. Everyone wins. Injured children are compensated fairly and swiftly. Consumers and taxpayers are spared onerous extra costs. The manufacturer is rewarded for any reduction in risk associated with the product. Those who are most directly responsible for the problem are those who will pay for it.

IV. DISCUSSION OF ADDITIONAL MAJOR PROVISIONS OF P.L. 99-660

Reporting requirements and penalties for violations

The Act institutes requirements for the recording and reporting of information on vaccine administration by health care providers and manufacturers. This includes recording and reporting of adverse reactions and significant problems encountered in the production, testing or handling of vaccines.

However, for the reporting mechanism to be effective, there must be stringent enforcement. Connaught advocates the imposition of penalties for all compliance failures. The penalty amounts for unintentional violations naturally would be far lower than existing levels for intentional or fraudulent violations.

Connaught advocates a direct accountability system that will depend upon accurate and comprehensive reporting. However, the reporting mechanism will not be in place at the outset of the compensation program.

Connaught would not be opposed to a temporary market-share funding contribution, prior to the establishment of the reporting mechanism. This contribution would be necessary only for the first year of the compensation program's operation,

or until sufficient data are compiled for accurate management of the Direct Accountability system.

Government standards defense

Under the current law, a manufacturer will not be held liable for punitive damages in a civil proceeding brought after a claimant has rejected the compensation award, if the manufacturer can show that it complied "in all material respects" with Federal requirements. This is the "government standards defense."

Because evaluation of this standard is subject to broad and inconsistent interpretation from state to state, Connaught believes the term "in all material respects" must be specifically defined or omitted entirely, to avoid judicial confusion. If the defense is to have its intended effect, manufacturers must be fully protected from punitive damages when they have complied with appropriate regulatory standards.

Connaught further proposes that the government standards defense be extended to include product liability actions against the manufacturer. Of particular concern are so-called "design defect" cases. Without a government standards defense in this area, it is possible that a devastating number of claims could be brought against U.S. manufacturers on the grounds that there are other safer, better or more technologically advanced DTP vaccines available.

In order to prevent this potentially disastrous consequence, the government standards defense should, at a minimum, be extended to design defect cases.

In sum, the recommendations on government standards defense will yield greater predictability regarding liability. This, in turn, can help stabilize vaccine price and insure supply. Otherwise, prices could rise to cover increased liability; worse, manufacturers could abandon the market. The recommendations will help avoid both devastating levels of awards and a high volume of lawsuits.

In the event that the government standards defense for punitive damages is not improved, Connaught proposes the institution of reasonable caps on punitive damages if claimants elect to bring an action in state court.

One of the stated purposes of the law is to stabilize the vaccine market, thereby insuring constant supply. One way to accomplish this is to establish some equitable limit on potential liability exposure. Although caps on punitive damages are controversial, Connaught proposes the establishment of a reasonable absolute limit on punitive damage awards for actions brought outside the compensation system.

Limits on pain and suffering awards in civil cases

The law limits pain and suffering awards to $250,000 for claimants who remain in the compensation system. For those claimants who pursue remedies in civil court, Connaught proposes a similar cap on non-economic damages. Such a cap would increase the number of claimants who elect to stay in the system, providing greater certainty for manufacturers with respect to liability exposure, and ultimately helping to stabilize the vaccine marketplace.

Retroactivity of compensation

The law provides that the first 3,500 petitions filed by claimants before the effective date of the Act will be entitled to compensation.

As an alternative, Connaught suggests the application of retroactive compensation to reimbursable expenses that are incurred within a specified number of years prior to enactment of the law.

There are several benefits to this approach. First, it avoids the potential problem of filing of spurious claims and a resulting "race to the courthouse." It can be argued that individuals with the most meritorious claims may well be inclined to seek civil remedies and avoid the compensation system. Thus, the majority of no-fault claims filed could be of marginal validity. If this is the case, the result could be increased liabilities in both the civil and government compensation systems—a disorderly, costly and inequitable outcome that the law was intended to prevent.

Connaught's suggestion would allow manufacturers to better predict their liability. It would increase the likelihood of meritorious claims being settled rather than litigated. It would promote a more orderly proceeding for potential claimants.

Connaught also proposes that retroactive claims apply to a manufacturer only for the time that manufacturer has been in the vaccine market. Connaught has been in the DTP market for just nine years. Yet current law would make us accountable for claims arising *before* the company ever produced DTP vaccine. In effect, we would be subsidizing other manufacturers.

To help insure accountability and fairness, Connaught proposes the establishment of a mechanism for retroactive claims which attempts to distinguish among manufacturers.

Insufficiency of funds

The law states that if at any time there are insufficient funds to pay for claims for the next 180 days, the compensation system shall cease to be in effect until sufficient funds to pay for all of the claims become available.

Connaught advocates that some backup funding be made available in the event of insufficient funds under the system. Alternatively, limitations could be placed on the number of claims which can be transferred to the state courts.

By the time P.L. 99-660 was enacted, a provision had been deleted which would have allowed federal borrowing if there were sufficient funds. We believe this omission effectively confounds the purpose of the compensation program: to provide ready means of compensation for injury victims while affording manufacturers more predictable levels of liability.

Without the borrowing mechanism, all claims filed under the compensation system could be immediately transferred to the state courts for adjudication, thus increasing the total number of claims filed by injured parties and placing manufacturers in an even more precarious position.

Table of injuries

P.L. 99-660 includes a list of all possible adverse reactions to a vaccine. Connaught believes that the injury table, as currently structured, is far too broad. It permits virtually any reaction to qualify for compensation.

We believe this situation could create an open-ended fund for problems that are not related to or are independent of the administration of the vaccine. For example, in the intervening period of two months between each of the three standard DTP injections, children can often contract infections that produce high fevers, convulsions and other symptoms that are totally unrelated to the vaccine. Under the law, however, these conditions could be attributed to the vaccine, thereby qualifying for compensation. The net result could be an overburdned, slow-moving system that fails in its intention to provide just and speedy compensation for injured children.

Connaught proposes elimination of the table of injuries, in favor of requiring proof of a causal relationship between the injury and the administration of a vaccine in order to qualify for compensation. As noted above, such a system is included in the Madigan proposal.

SUMMARY

Connaught supports the federal compensation system for children injured by vaccines. We believe manufacturers should assume the burden of responsibility and the cost of this compensation.

We also recognize, however, the significant difficulties with which Mr. Waxman's Subcommittee grappled in crafting what is now P.L. 99-660. And we are mindful of the complexities with which this Subcommittee must deal in developing a fair and efficient funding mechanism—one that assures supply, controls costs and gives victims their just due.

Hopefully, our comments will be considered as the Subcommittee attempts to fashion a solution and advances us toward the goal that everyone—parents, physicians, government and manufacturers—is seeking. While we are talking in economic terms, the real meaning of our discussion is the protection of human lives.

Connaught stands ready to help in solving this problem.

We thank you for the opportunity to participate in the dialogue on this vital public health issue.

Mr. COYNE. This question is directed to each of the panelists, have you set up liability reserves to be used in the event of damage awards?

Mr. JOHNSON. Yes, we have and those reserves have varied as our insurance coverage was changed; beginning in 1985, we virtually lost all of the liability insurance coverage that we had and that was the point in time when our major price increase took place on DPT.

Mr. COYNE. So your company does have a reserve set up.

Mr. MACMASTER. We do not have a reserve set up. We have insurance; we've had insurance. We have not increased our price to put a factor on the need for the need for potential reserve.

Mr. WILLIAMS. Yes; our current liability exposure is being covered almost entirely by reserves.

Mr. COYNE. Would each of you be willing to provide the subcommittee with such information on such reserves as well as information related to lawsuits filed against you, including settlement results.

Mr. JOHNSON. Certainly, recognizing there may be some limitations that the court has imposed as far as settlement information, but we will make available what we can.

Mr. WILLIAMS. Yes; but we would also be bound by similar restrictions.

[The following was subsequently received:]

CONNAUGHT LABORATORIES, INC.,
Swiftwater, PA, March 27, 1987.

Mr. JOSEPH K. DOWLEY,
Chief Counsel, Committee on Ways and Means,
Longworth House Office Building, Washington, DC.

DEAR MR. DOWLEY: Attached are the responses requested of Connaught Laboratories at the hearing of Thursday, March 5, 1987, before the Subcommittee on Select Revenues of the Committee on Ways and Means.

As I recall, the Subcommittee requested information regarding liability reserves of Connaught, the number of lawsuits filed against Connaught, and settlement and court judgment data.

The information supplied does not include confidential information that could seriously prejudice Connaught's position in the numerous pending and anticipated DTP liability suits.

1. *Liability Reserves.*—As stated at the hearing, Connaught has established liability reserves due to the significant reduction in available limits of insurance for its products. In the past few years, Connaught has been able to obtain only spotty third party insurance coverage. The current policy is written on a claims-made basis with a 17 million dollar deductible. As a result, Connaught is essentially self-insured.

2. *Number of Lawsuits Filed.*—Since 1982, there have been approximately 120 lawsuits filed against Connaught Laboratories for claims relating to the administration of DTP vaccine. The number of suits per year has dramatically increased. For example, in 1982, 4 lawsuits were filed against Connaught claiming 40 million dollars in damages. In 1985, the number of suits filed was 47, and in 1986, 54 suits had been filed as of January 8, 1987. In 1985 and 1986 combined, the damages claimed against Connaught exceeded one billion dollars.

3. *Court Judgments and Settlement Results.*—Because of our precarious insurance condition, Connaught thru its insurers settled several of the lawsuits brought against it in recent years. However, Connaught has attempted to have all settlement agreements filed in court placed under seal because disclosure of these amounts will increase the cost of settling future cases. Experience has shown that when the amounts paid in early settlements are disclosed, claimants and their attorneys generally refuse to accept less than the average prior settlement and often will insist on bettering that average. As a result, disclosure of settlement awards creates a strong upward pressure on future settlement payments and increase the cost of claims to the company and to the future consumers of its product. Therefore, Connaught cannot provide specific information regarding settlement results.

Notwithstanding this limitation, a comparison of price increases and increases in litigation expenses incurred by Connaught does provide insight into the dramatic escalation in liability related expenses. Connaught's catalogue price for DTP vaccine has increased from $4.67 per vial in January of 1983 to $162.67 per vial in July of 1986, an increase of almost 3,500 percent. By comparison, the company's total DTP vaccine litigation expenses (including all settlements, judgments, legal fees, and related expenses) increased by 18,360 percent. Defense costs alone (including all legal fees and related expenses for representation of Connaught but excluding all settlements, judgments, and payment of claimant's attorneys fees) have increased by 3,800 percent from 1983 to 1986. While this trend-type data does not disclose specific settlement results, it does demonstrate that price increases for DPT vaccine are closely related to increased liability exposure.

On behalf of Connaught, I appreciated the opportunity to testify before the Subcommittee on Select Revenues, and renew my offer of cooperation and assistance in

the future. If you have any questions or comments regarding these responses, please do not hesitate to contact me at (717) 839-7187, or Mr. Timothy Jenkins of O'Connor & Hannan at 887-1400.

Sincerely,

DAVID J. WILLIAMS,
Vice President and General Manager.

Mr. COYNE. We want to thank you for your testimony. We will now move on to the next panel.

The next panel consists of Andrew D. McBride and M. Roy Schwarz. Mr. McBride, you may proceed.

STATEMENT OF ANDREW D. McBRIDE, M.D., SENIOR VICE PRESIDENT OF ADVOCACY, CHILDREN'S HOSPITAL NATIONAL MEDICAL CENTER, WASHINGTON, DC, ON BEHALF OF NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS AND RELATED INSTITUTIONS

Dr. MCBRIDE. Good morning, Mr. Chairman, and members of the subcommittee.

I am Dr. Andrew McBride, senior vice president of advocacy at Children's Hospital National Medical Center in Washington, DC. I am appearing on behalf of the National Association of Children's Hospitals and Related Institutions, NACHRI. I am here as a child health advocate and a former public health official, having served as Commissioner of Public Health for the District of Columbia. I appreciate the opportunity to testify on this vital issue.

NACHRI represents 94 children's hospitals, and we are on the front lines of the child vaccine issue. Many children's hospitals such as mine are located in urban areas and are the primary source of health care for thousands of children. Children's hospitals administers a wide range of vaccines including diphtheria, polio, tetanus, mumps, measles, and several flu vaccines. In our hospital alone, we provided over 10,000 vaccines in 1986. Children's hospitals see what happens to children who are not vaccinated as well as we see the rules of what happens to those few who do come down with untoward effects of the vaccine. Finally, because Children's hospitals do administer the vaccines, we are also exposed to the legal liabilities that are so much a part of this problem.

As members of the committee are aware, the problem at hand is that our Nation's vaccine supplies have been drastically reduced, and the cost of some vaccines have skyrocketed. Because of increased litigation stemming from adverse reactions by some children to some vaccines, many manufacturers have withdrawn from production of these vaccines, reducing the supply. In fact, vaccine stockpiles are severely below the recommended level prescribed by CDC.

Sadly, the recent attention is causing parents to express concern about having their children immunized and, in some cases, parents are delaying immunization.

I might parenthetically add here the experience of England in the early 1980's where there was a great deal of concern about the pertussis vaccine and its untoward effect in which pertussis vaccinations were, indeed, decreased and there was an outbreak of experience in England of pertussis at this time. I think we are seeing a similar circumstance here.

73-717 O - 88 - 5

Although most schools require immunization, there is a delayed immunization that keeps children at risk. This is often referred to as the toddler gap in which children during infancy are immunized and during the toddler stage go underimmunized and then become immunized on school entry.

Clearly, this is a child health issue as well as a public health issue that needs to be addressed by the Congress and action must be taken now.

After months of negotiations, the 99th Congress led by Congressman Waxman crafted a delicately balanced solution to the vaccine problem that gained support of all parties involved. Passed in the midnight hours, this compromise was part of Public Law 99-660, the Omnibus Health Care Package, the details of which I need not go into here. The critical issue still remains, however, that of financing the vaccine compensation program, the subject of this hearing.

We strongly believe that the financing mechanisms contained in the compromise—a surcharge on the vaccines— is the most fair, practical and direct way to establish the supporting trust fund. We would be concerned, however, if this surcharge became excessive. We would like to see a cap on this of no more than $5 per dose. We also agreed that putting a surcharge in place 6 months before the implementation of the compensation program would build up a reserve and thereby relieve the burden on the U.S. Treasury to fund the program.

As you know, the Academy of Pediatrics has taken a lead in investigating the financing of this program, and we fully support their efforts.

Mr. Chairman, modern medicine has proven that it can conquer the spread of deadly infectious diseases. Today in the United States, we rarely see a case of small pox, cholera or yellow fever. However, such good public health records can only be maintained through vigilance.

Perhaps the best example is our conquest of infectious disease is in the development of the polio vaccine in the early 1950's which has all but eliminated this crippling disease in children and young adult in the past 30 years. Tragically, however, as a society, we have let down our guard and, in some areas of this country, the incidence of polio is on the rise because of the lack of complete immunization. This clearly argues for a sustained comprehensive vaccination program.

In conclusion, the AIDS epidemic has dramatically and graphically reminded us that modern society is susceptible to infectious fatal diseases. While there is no vaccine or cure for AIDS, there is hope that a vaccine will be developed in the near future. When that happens, we trust that this country will have demonstrated its commitment to a safe and effective vaccine program.

In the meantime, there are many diseases from which we can protect ourselves and our children. We should also use all the means at hand to do so. Maintaining our vigilance against disease comes at a cost, but surely we must be able to afford the health of our population.

Thank you.

Chairman RANGEL. Thank you.

Our next witness is M. Roy Schwarz of the American Medical Association.

STATEMENT OF M. ROY SCHWARZ, M.D., ASSISTANT EXECUTIVE VICE PRESIDENT FOR MEDICAL EDUCATION AND SCIENCE, AMERICAN MEDICAL ASSOCIATION, ACCOMPANIED BY ROSS RUBIN, DIRECTOR, DEPARTMENT OF FEDERAL LEGISLATION

Dr. SCHWARZ. Mr. Chairman and members of the subcommittee, my name is M. Roy Schwarz. I am the assistant executive vice president for medical education in science of the American Medical Association. Accompanying me today is Mr. Ross Rubin on my right, your left, who is director of AMA's department of Federal legislation.

The AMA is pleased to testify before this committee concerning funding of the vaccine injury compensation program established under Public Law 99-660.

For a number of years, the AMA has been very interested and concerned about the issue of vaccine injury compensation. We have consistently expressed support for the establishment of an equitable vaccine compensation system that achieves the following five goals:

First, the assurance of appropriate immunization for all children;

Second, the development of safer vaccines;

Third, the equitable compensation of persons severely injured by reactions to mandated pediatric vaccines;

Fourth, the assurance of continued vaccine development and availability of mandated pediatric vaccines; and

Fifth, the assurance of continued participation by physicians and other qualified persons in the administration of mandatory pediatric vaccines.

The AMA supported the enactment of the modified no-fault vaccine compensation program created by Public Law 99-660. We believe the program meets many of the goals I have just outlined. However, since Public Law 99-660 does not include a funding mechanism, further congressional action is required. We believe strongly that Congress should expeditiously pass legislation to fund the vaccine compensation program. Until Congress acts, the ongoing crisis of vaccine availability, costs and liability will persist.

Funding for the compensation program should come from the broadest source possible. The entire population, not just those immunized, benefit from full participation in pediatric immunization programs and should bear these costs. Spread over the entire population, the cost per capita for a compensation fund would be low. The smaller the taxing base, the higher the cost per individual. Use of a broad-based financing plan such as general Federal revenues would also obviate the need for an added surcharge for each vaccine. Such a surcharge would discourage full participation in childhood immunization programs by increasing the cost of vaccines.

The AMA recognizes, however, that due to serious budgetary constraints, Congress may not rely on general Federal revenues to fund the compensation program. As an alternative financing mechanism, a premium could be added to the purchase price of each

dose of each mandatory childhood vaccine. The premium should be the same for all mandatory childhood vaccines. Distributing the costs over all vaccines would insure that the surcharge on each dose would be relatively modest and, thus, not significantly discourage participation in the immunization program.

The premium should also be payable by all purchasers of mandatory pediatric vaccines including the Centers for Disease Control. Again, since all of society benefits from immunization programs, the cost of compensating an injured person should be spread over as broad a base as possible.

As I stated earlier, the AMA supports the enactment of the vaccine compensation program created by Public Law 99-660. However modifications in the law are needed to insure that the compensation program is equitable and results in more predictable costs.

In my written statement, I have discussed the issue of protection for those who administer the vaccine, and I would draw your attention to that discussion. We also believe that the vaccine compensation law should be amended to include a reasonable limit on awards for pain and suffering under the tort system. As enacted, the law includes such a limit only on pain and suffering awards under the compensation system. A reasonable limit is needed on awards for pain and suffering to insure that the vaccine manufacturers' costs are predictable.

In concluding, Mr. Chairman, we would urge Congress to promptly pass legislation to fund the vaccine compensation program. Funding for the program should come from the broadest possible source since all of society benefits from full participation in pediatric immunization programs.

In addition, we urge to you to recommend modifications to the vaccine compensation law to establish a reasonable limit on awards for pain and suffering under the tort system.

Mr. Chairman, I want to commend you and your interest in this important issue of funding for the vaccine compensation program. The AMA would be happy to work with you and your staff in developing an equitable funding mechanism for the program.

Earlier this morning, we heard discussions from others about the unrecognized adverse reactions that occur with vaccine compensation. With your permission, Mr. Chairman, I would like to introduce into the record a report that appeared in our Journal of the American Medical Association entitled, "Pertussis Vaccine Injury." It is the result of a panel of experts AMA impanelled to review this issue, and it discusses that issue directly.

I would be pleased to answer any further questions you might have.

[The prepared statement and attachment follow:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee on Select Revenue Measures
Committee on Ways and Means
U.S. House of Representatives

Presented by

M. Roy Schwarz, M.D.

RE: Funding of the Vaccine Injury Compensation Program

March 5, 1987

Mr. Chairman and Members of the Committee:

My name is M. Roy Schwarz, M.D. I am Assistant Executive Vice President for Medical Education and Science of the American Medical Association.

The AMA is pleased to testify before this Committee concerning funding of the vaccine injury compensation program established under P.L. 99-660.

AMA and Vaccine Injury Compensation

For a number of years, the AMA has been very interested in the issue of vaccine injury compensation. In 1983, the AMA convened a special Ad Hoc Commission on Vaccine Injury Compensation. The Ad Hoc Commission issued a report recommending that a federal, no-fault compensation program be established as the exclusive remedy for persons seriously injured as a result of mandated pediatric immunizations. The AMA then developed draft federal legislation to implement the Commission's recommendations.

Over the past three years, the AMA has testified before Congressional committees concerning the issue of vaccine injury compensation on six occasions. We have expressed support for the establishment of an equitable vaccine compensation system that achieves the following five goals:

1. the assurance of appropriate vaccination of all children;

2. the development of safer vaccines;

3. the equitable compensation of persons severely injured by reactions to mandated pediatric vaccines;

4. the assurance of the continued development and availability of mandated pediatric vaccines; and

5. the assurance of continued participation by physicians and other qualified persons in the administration of mandatory pediatric vaccines.

The AMA supported the enactment of the modified no-fault vaccine compensation program created by P.L. 99-660. We believe that the program meets many of the goals I have just discussed. It should ensure that seriously injured persons are promptly and fairly compensated. It should also result in reduced liability costs for vaccine manufacturers and thus

help assure a continued adequate supply of vaccines. Finally, the research and coordination provisions of the law should work to encourage the development of improved pediatric vaccines. Since P.L. 99-660 does not include a funding mechanism, further Congressional action is needed to activate the compensation program.

Funding for the Compensation Program

We believe strongly that Congress should expeditiously pass legislation to fund the vaccine compensation program. Until Congress acts, the on-going crisis of vaccine availability, cost and liability will persist.

Funding for the compensation program should come from the broadest source possible. The entire population, not just those immunized, benefits from full participation in pediatric immunization programs and should bear these costs. Spread over the entire population, the cost per capita for a compensation fund would be low. The smaller the taxing base, the higher the cost per individual. Use of a broad-based financing plan, such as general federal revenues, would also obviate the need for an added surcharge on each vaccine. Such a surcharge could discourage full participation in childhood immunization programs by increasing the cost of vaccines.

The AMA recognizes, however, that due to serious federal budgetary constraints, Congress may not rely on general federal revenues to fund the compensation program. As an alternative financing mechanism, a premium could be added to the purchase price of each dose of each mandatory childhood vaccine. Revenue raised could be deposited in a vaccine compensation trust fund and used to pay claims under the program. (Until an adequate fund reserve is established, the program could be funded by a loan from the federal government.) The premium could be set at an amount equal to the total estimated benefits and administrative costs of the program for that year. In addition, the premium could be adjusted each year to reflect differences between the projected costs and premium collections in the previous calendar year.

The premium imposed should be the same for all mandatory childhood vaccines. Distributing the cost equally over all such vaccines should ensure that the surcharge on each dose would be relatively modest and thus not significantly discourage participation in immunization programs.

The premium should also be payable by all purchasers of mandatory pediatric vaccines, including the Centers for Disease Control. Again, since all of society benefits from immunization programs, the cost of compensating injured persons should be spread over as broad a base as possible.

AMA - Recommended Modifications

As I stated earlier, the AMA supported the enactment of the vaccine compensation program created by P.L. 99-660. However, modifications in the law are needed to ensure that the compensation program is equitable and results in more predictable costs.

As enacted, P.L. 99-660 prohibits direct tort actions against vaccine manufacturers, but not against those who administer vaccines. Without such protection, health professionals may be viewed as the new "deep pocket" and thereby face an increased number of liability suits. Such suits would discourage the continued participation by physicians and other qualified persons in the administration of mandatory pediatric vaccines.

The AMA, therefore, urges strongly that the law be amended to offer the same protections to those who administer vaccines as are available to those who manufacture them. The act should be modified to require a vaccine-injured person to pursue recovery under the compensation program prior to any tort action.

We also believe that the vaccine compensation law should be amended to include a reasonable limit on awards for pain and suffering under the tort system. As enacted, the law includes such a limit only on pain and suffering awards under the compensation program. A reasonable limit is needed on awards for pain and suffering to ensure that vaccine manufacturers' costs are predictable.

Conclusion

We urge Congress to promptly pass legislation to fund the vaccine compensation program. Funding for the program should come from the broadest possible source since all of society benefits from full participation in pediatric immunization programs. In addition, we urge you to recommend modifications to the vaccine compensation law to protect health professionals who administer vaccines and to establish a reasonable limit on awards for pain and suffering under the tort system.

Mr. Chairman, I want to commend you for your interest in the important issue of funding for the vaccine injury compensation program. The AMA would be happy to work with this Committee in developing an equitable funding mechanism for the program. I would be pleased to answer any questions Members of the Committee may have.

Reprinted from the JAMA® Journal of the American Medical Association
December 6, 1985, Volume 254
Copyright 1985, American Medical Association

AMA Panel Report

Pertussis Vaccine Injury

AMA Ad Hoc Panel on Pertussis Vaccine Injury

IN AN effort to ensure an adequate and uninterrupted supply of vaccines for mandated pediatric immunization and to encourage the continued timely administration of these vaccines, the American Medical Association formed a commission to explore the need for a compensation system for vaccine-injured patients. From these deliberations recommendations for federal legislation were made and approved by the Association's House of Delegates in June 1984. Draft federal legislation was prepared calling for the establishment of a federal vaccine compensation program as an exclusive remedy for those seriously injured by mandated vaccines. There was considerable urgency since the number of national suppliers for one of these vaccines (diphtheria-tetanus-pertussis, or DTP) decreased from three to one. There also was a reasonable possibility that the sole remaining supplier would be unable to obtain insurance renewal.

The concern with DTP vaccine resides with its pertussis cell components, which occasionally induce severe neurological injury. In order to prepare an appropriate information base on potential pertussis vaccine injuries in the context of Congressional consideration of vaccine injury compensation legislation, an ad hoc panel was formed to prepare a report to identify (1) severe irreversible vaccine reactions and the criteria for attributing such reactions to the DTP vaccine and (2) the severe, reversible DTP reactions, their likely duration and sequelae, and the clinical criteria for attribution. Within the purpose of this report, stringent proof of causation by the vaccine was not required. The panel also addressed the question of injuries reputed to be vaccine related by television and radio news programs, newspapers, or parents' groups but whose relationship to DTP vaccine is not necessarily supported by medical evidence.

From the Ad Hoc Panel on Pertussis Vaccine Injury, American Medical Association, Chicago.
Reprint requests to Department of Drugs, American Medical Association, 535 N Dearborn St, Chicago, IL 60610 (Dr Lampe).

SERIOUS PERTUSSIS VACCINE INJURIES THAT MAY PRODUCE SEQUELAE OF LONGER THAN ONE YEAR'S DURATION

Encephalopathy

This is characterized by *generalized nonfebrile toxic convulsions* (distinct from infantile spasms) with states of *diminished consciousness* (other than postictal state) and a *personality change* that may be difficult or impossible to determine in an infant. The personality change may not, therefore, be a necessary criterion for diagnosis of encephalopathy. To be related to vaccine administration, the encephalopathy must have no other demonstrable cause (eg, meningitis) and must occur within 72 hours of the vaccine administration. In these cases, the infant will be so demonstrably ill that any prudent parent will seek medical care during the acute encephalopathy. (Encephalitis is defined as the above with the additional feature of the presence of cells in the spinal fluid.)

It was the opinion of the panel that the probability of encephalopathy being considered a *possible* adverse reaction to pertussis vaccine is 100%. In any specific case of encephalopathy related to vaccine administration, there is about a 60% to 70% level of probability of vaccine causation; about one in three may have residual brain damage after one year.

Complex Febrile Convulsions

These are seizures developing in relationship to fever occurring in an infant, who apparently is otherwise developmentally and neurologically normal, that are of longer than ten minutes' duration *or* are repetitive over 24 hours *or* are of focal nature.

To be vaccine related, the fever must have no other demonstrable cause and both the fever and seizures must occur within 24 hours of vaccine administration.

It was the opinion of the panel that the probability that complex febrile seizures related to vaccine administration may occur as an adverse response is 100%, but the confidence that any particular case may have

The Panel members were Gerald A. Fenichel, MD, Vanderbilt University, Nashville, Tenn; Edward A. Mortimer, MD, Case Western Reserve University, Cleveland; and James F. Schwartz, MD, Emory University, Atlanta. Alan R. Hinman, MD, acted as a liaison member representing the Center for Communicable Diseases of the Centers for Disease Control, Atlanta. Kenneth F. Lampe, PhD, was the AMA staff secretary.

had such injury will depend on the individual patient and the nature and thoroughness of the medical evaluation. It was the impression of the panel that about 10% of patients exhibiting complex febrile seizures may have residual brain damage after one year.

Afebrile Convulsions

These are generalized tonic-clonic seizures of less than 30 minutes' duration developing in the absence of fever.

To be pertussis vaccine related, the seizures must develop within 72 hours of administration in a patient with no evidence of preexisting neurological damage.

The opinion of the panel is that the probability of such an event being an adverse effect of the vaccine was probably 50% to 70%, and for any individual case was less than 30%. More than two thirds of the cases are likely to have etiologies other than the vaccine. The probability that the vaccine could act as a trigger for an underlying convulsive disorder is less than 50%. There are no data from which sequelae can be predicted; each case would require individual expert medical evaluation.

SERIOUS PERTUSSIS VACCINE INJURIES UNLIKELY TO HAVE SEQUELAE PERSISTING FOR ONE YEAR

Simple Febrile Convulsions

This is a single, simple generalized seizure of less than ten minutes' duration, occurring with fever in a child who is otherwise developmentally and neurologically normal.

To be vaccine related, the fever must have no other demonstrable cause and both the fever and the seizure must occur within 24 hours of vaccine administration. These febrile seizures may occur after any vaccination and are not specific for pertussis vaccine.

It was the opinion of the panel that the probability of simple febrile convulsions being the result of pertussis vaccine administration is 100%. The probability that vaccine administration is the etiology in a single case, if meeting the above criteria, is 100%. It was the further opinion that the probability is 100% that there will be no persistent sequelae.

Anaphylaxis

This is defined as an exaggerated allergic reaction to foreign protein occurring within two hours of administration.

It was the opinion of the panel that the probability that such reaction could be associated with pertussis vaccine is 100%. It was the panel's further opinion that sequelae to such an event are unlikely.

Shock Collapse

The available published cases of shock collapse describe a shocklike episode with signs of vascular collapse, muscle hypotonicity, and unresponsiveness for ten or more minutes, with or without fever, but *without* paralysis or seizures.

This condition is not a specific pertussis vaccine-related event but has been reported with other vaccines. In all described cases, recovery is complete without sequelae. Shock collapse occurs within 24 hours of vaccination.

It was the opinion of the panel that the probability that shock collapse is a possible adverse event to vaccine administration is high (possibly 100%) and that for a specific case of shock collapse, the linkage to vaccine administration is greater than 70%.

The probability that any of the following are pertussis vaccine related was considered 0% by the panel: serum sickness; aseptic meningitis; sudden infant death syndrome (SIDS); Reye's syndrome; peripheral mononeuropathy; transverse myelitis; arthritis/arthralgia; Guillan-Barré syndrome; juvenile diabetes; non-SIDS sudden death; thrombocytopenic purpura; infantile spasms (the panel noted that the risk of developing infantile spasms is *not* affected by pertussis immunization, but that the frequency of infantile spasms may be increased during a 72-hour period following administration); acquired hemolytic anemia (the panel noted there is a single anecdotal report from Norway that this condition occurred following vaccination, but there is no objective evidence that the anemia is actually vaccine related); chronic brain syndrome *in the absence* of acute encephalopathy (this would include all possible manifestations, eg, learning disabilities, autism, hyperactivity, mental retardation, and epilepsy).

The panel noted also that there is no evidence that killed vaccine (such as pertussis vaccine) can cause any prolonged, insidious, delayed deleterious effects (in contrast to live, attenuated organism vaccines).

Printed and Published in the United States of America

Chairman RANGEL. Mr. Coyne.

Mr. COYNE. I have no questions.

Chairman RANGEL. Does the American Medical Association support the bill in its present form?

Dr. SCHWARZ. Yes. While it does not address all of our concerns, we supported its enactment.

Chairman RANGEL. Does the bill in its present form put reasonable limits on awards for pain and suffering under the tort system?

Mr. MCBRIDGE. No.

Chairman RANGEL. Thank you very much. I appreciate the fact that both of you have offered to work with the committee. I think we will need additional help.

The last panel, Dr. Morris, chairman of the board of governors of the Bell of Atri; the legislative director of the Help Abolish Legal Tyranny, Deborah Chalfie; and Marge Grant, who is the president of the Determined Parents to Stop Hurting Our Tots.

Dr. Morris.

STATEMENT OF J. ANTHONY MORRIS, PH.D., CHAIRMAN, BOARD OF GOVERNORS, BELL OF ATRI, INC., COLLEGE PARK, MD

Mr. MORRIS. My name is J. Anthony Morris. I am chairman of the governing board of the Bell of Atri, a public interest organization concerned with health, science, and public policy.

I want to thank you for the opportunity to testify in opposition to funding of the Childhood Vaccine Program.

My interest in development and use of vaccines goes back more than 40 years; 30 of those years were spent as research virologist in vaccine study at the National Institutes of Health and at the Food and Drug Administration.

Those 30 years encompassed the swine flu episode during which, in 1976 and 1977, representatives of medical societies, vaccine manufacturers and insurance companies testified in hearings before House and Senate subcommittees. The representatives of medical societies and vaccine manufacturers gave the impression that the number of people expected to suffer serious adverse effects attributable to swine flu vaccine injection would be small.

Representatives of insurance companies testified that that number was indeterminate and that companies they represented would not write insurance for the proposed swine flu vaccine program because risks could not be estimated with a meaningful degree of accuracy. As a consequence, the Federal Government assumed the risks, having been assured by testimony from representatives of medical groups and vaccine manufacturers that the number of people to suffer serious side effects from swine flu vaccine injection would be small and the payout in dollars would be negligible.

The latest records in the Bell of Atri files were obtained from the Department of Justice in August 1982, or about 6 years after the termination of the swine flu vaccination program. These show that as of August 1982, 1,571 lawsuits had been filed by individuals who claimed to have suffered serious adverse reactions from swine flu vaccine injection. Of these suits:

290 were closed either by stipulation, trial or settlement with a payout by the Federal Government of $57,000,000.

693 lawsuits were still pending in 1982 or 6 years after the vaccine program was stopped, with an amount requested by plaintiffs of $1,027 million.

588 lawsuits [the difference between 1,571 and 939 (290 + 693)], we assume were dismissed, although the Department of Justice records sent to us did not show this.

These figures give some idea of the consequences resulting from a program in which the Federal Government assumes liability of a product known to produce in an indeterminate number of recipients, serious damage to health—while the producer and user of the product benefit from profits and professional fees, but are shielded from responsibility for the product and for its administration to the recipient.

In 1977, in testimony before the House Subcommittee on Health and the Environment, at a hearing on review and evaluation of the swine flu program, I testified that when I left the Food and Drug Administration in 1976, there was no available technique to measure reliably and consistently neurotoxicity or potency of most of the vaccines then in use, including DPT vaccine.

Today, 11 years later, the situation remains essentially the same.

And, today, this subcommittee is considering a funding mechanism for a vaccine injury compensation program. But this program also provides a protective shield to vaccine manufacturers. It eliminates any obligation for the manufacturers to warn directly a vaccine recipient, or parents of a vaccine recipient, of the risks involved in vaccine injection. It transfers this responsibility to the health care provider. I ask the question: How many health care providers will transmit to parents of children, prior to pertussis vaccine injection, the information presented by Dr. E.A. Mortimer, a member of the U.S. Advisory Committee on Immunization Practices, to a medical group?

I quote:

> Few physicians doubt that pertussis vaccine occasionally produces severe reactions with permanent sequelae or death. Unfortunately, the frequency of these severe reactions is not precisely known (International Symposium on Pertussis, Proceedings of a Conference. DWHE Publication No. (NIH) 79-1830, p. 152).

I answer the question: very few.

This program also limits compensation for past and future reimbursement to $250,000, an amount that hardly begins to meet medical and care expenses as one who, as a result of DPT vaccine injection at 2, 4 or 6 months of age, is left mentally and physically retarded for a lifetime.

Even with this limitation of compensation, the executive vice president of Dissatisfied Parents Together, a group that is a proponent of the Childhood Vaccine Injury Act, wrote in a letter to the Washington Post, Health Section, 10 February 1987, that:

> Five more years of American children dying and becoming brain damaged by the current 45-year-old [DPT] vaccine is not only an unnecessary human tragedy, it could well bankrupt the federal vaccine injury compensation system recently approved by Congress.

So, even before a funding mechanism is set up for a compensation system, its bankruptcy is foreseen by a proponent of the compensation system.

The vaccine compensation program will not become effective until Congress adopts a funding system.

My urgent plea to the members of this subcommittee is: Do not fund the compensation program of the National Childhood Vaccine Injury Act of 1986. This program, in my judgment, will be found to be a black hole for taxpayers' dollars, to be an escape from just responsibility by manufacturers and medical practitioners for their product and their practices, and to be an injustice to children who will be irreparably harmed by mandated vaccine injections.

Rather, money and efforts should be directed towards reduction or elimination of the need for funding of a seriously flawed compensation system. Money and effort should be directed towards improving vaccines and improving vaccine delivery systems, not towards funding a seriously flawed compensation system to pay for damage that should and can be prevented.

Thank you for your attention.

Chairman RANGEL. Our next witness is Deborah Chalfie, legislative director of HALT.

STATEMENT OF DEBORAH CHALFIE, LEGISLATIVE DIRECTOR, HELP ABOLISH LEGAL TYRANNY [HALT]—AN ORGANIZATION OF AMERICANS FOR LEGAL REFORM

Ms. CHALFIE. Thank you very much, Mr. Chairman, for giving HALT the opportunity to testify today and offer our views on a funding mechanism for the childhood vaccine injury compensation program.

You may not be aware of what HALT does. We are a national, in fact, the only national organization for consumers of legal services and users of the legal system. We have 130,000 members nationwide, and through education and advocacy we seek to enable people to dispose of their legal affairs more simply, affordably, and equitably than they can now in the legal system.

We have been active in the national debate over tort reform because we believe that the tort system as it exists today is agonizingly slow, unduly expensive and, unfortunately, an unpredictable lottery for people on both sides of a lawsuit. We have participated in the hearings on the Senate side over product liability and in this chamber on the early versions of a vaccine compensation bill.

We enthusiastically supported H.R. 5184 and also Public Law 99-660 not because we thought it was a perfect bill but because we thought it was the best attainable compromise. Other witnesses have told you that it was a long, hard process to reach a compromise. All of the parties involved think the bill could be better. HALT also had suggestions for improvements when Representative Waxman first introduced H.R. 5184.

This is not to say that the bill could not be improved from everyone's perspective, but I sincerely urge you to resist the temptation to tinker with the bill's provisions, either on the side of compensation or liability. I do that because the compensation program that did come out of this last Congress achieved a rather delicate bal-

ance between all of the interests involved, and to begin tinkering with that balance, I believe, is tantamount to killing the legislation and to killing the program.

As you have heard today victims of vaccine injuries have no choice but to go to the tort system to seek compensation for injuries. We sincerely believe that they need another choice.

We urge you to restrict your consideration to the funding mechanism only. As between the appropriations mechanism or an excise tax, we would favor an excise tax because we don't think it is appropriate that the fund be up for grabs on an annual basis. We think it is very important, as Mr. Schwartz said earlier, that if parents are going to be giving up their rights in the tort system, they need to have a fund they can count on to pay the expenses as they are incurred.

We do have some concerns about overcharging. As you have heard, some of the drug companies have set up liability reserve funds, a sort of self-insurance. That is something that we felt needed to be looked into when the compensation program was being considered.

But when you talk now about putting an excise tax on top of the liability fund, it seems to us that there is a big potential for overcharging. That is, assuming they pass this cost on to the consumer, drug companies are collecting money not only to go to the compensation fund but also for their own liability reserves. An injured victim can collect out of one or the other but not both.

In structuring the excise tax, if at all possible, we would urge you to either structure it so that manufacturers cannot pass that charge on or to put in some sort of provisions that would require the manufacturers to account for their liability reserves.

Just in closing, I wanted to say that these kinds of injuries that you have heard about today tend to be very severe and have even resulted in death. We are talking about a very important problem here, and we are hoping that the compensation program is part of the solution.

Again, I emphasize hope that the subcommittee and the full committee will restrict its consideration to the funding only and not relegislate the entire compensation program.

I would be pleased to answer any questions you might have.

Thank you very much.

[The prepared statement follows:]

Testimony of
Deborah Chalfie, Legislative Director
on behalf of
HALT -- AN ORGANIZATION OF AMERICANS FOR LEGAL REFORM
on
Funding for the Childhood Vaccine Injury Compensation Program
Created by P.L. 99-660
Presented to the
Subcommittee on Select Revenue Measures
of the
Committee on Ways and Means
U.S. House of Representatives
March 5, 1987

Chairman Rangel and members of the Subcommittee, thank you for affording HALT the opportunity to offer our views on funding for the Childhood Vaccine Injury Compensation program created by P.L. 99-660. I am Deborah Chalfie, Legislative Director of HALT -- An Organization of Americans for Legal Reform. HALT is a national, nonpartisan, public interest organization for legal consumers, with more than 130,000 members nationwide. Through education and advocacy, HALT seeks to enable people to dispose of their legal affairs more simply, affordably, and equitably than the legal system presently allows.

Amidst the national debate over tort reform, HALT has been a leading proponent of alternatives to a tort system that, from consumers' perspective, is an unduly slow and expensive lottery. In the states, HALT has been at the forefront of various efforts to enact no-fault auto insurance laws and streamlined, out-of-court compensation systems for patients injured in the course of receiving health care. In Congress, HALT participated in the long series of Senate hearings on proposals to create expedited compensation mechanisms for people injured by products. In this chamber, we also supported the creation of an alternative compensation scheme for those injured by childhood vaccines.

HALT enthusiastically supported H.R. 5184 (an earlier version of the compromise bill sponsored by Rep. Waxman that was ultimately included as part of P.L. 99-660) and urged President Reagan to sign the bill despite his misgivings. We did so not because we thought it was the perfect bill, but because, after years of work and false starts, it was the best attainable compromise. The provisions contained in P.L. 99-660 were carefully crafted to gain the support of several groups with diverse interests: parents, the medical profession, and pharmaceutical companies.

HALT urges you to restrict your consideration to the <u>funding mechanism</u> <u>only</u> and not to reopen the debate over this hard-won legislation. It is difficult to resist the temptation to tinker with its provisions, especially when, from any particular interest group's perspective, changes would "improve" the system. There are those who will certainly urge you to do so. But the balance of interests reflected in the law's provisions is a delicate one. To permit the legislation to be reconsidered is probably tantamount to killing the program altogether.

Of the funding mechanisms that have been discussed, the excise tax and related trust fund are far preferable to an annual appropriation because the latter places the program up for grabs on an annual basis. An excise tax on vaccines earmarked for the trust fund, on the other hand, ensures a stable source of funding that parents can count on. Besides, in light of the federal deficit, a new spending entitlement seems unwise when other alternatives are available.

As originally drafted, the Waxman compensation bill (H.R. 5184) specified particular amounts to be levied as surcharges on each dose of certain vaccines. It was assumed this surcharge would ultimately be passed on to consumers because the bill contained no provision to prevent it. To the extent that we all benefit from a reduction in the incidence of whooping cough, we should share the responsibility of compensating those who are "sacrificed" for that societal benefit.1/ But this should be the committee's second choice.

For two reasons, this committee's first choice in structuring the excise tax should be to require vaccine manufacturers to bear the cost of compensation without being permitted to pass it on, if at all possible. First, requiring manufacturers to bear the cost may provide an incentive to produce safer vaccines. Second, consumers have no choice about consumption: the innoculations are required by law. Because the manufacturers are profiting from a captive market, it is only fair for them, rather than consumers, to bear the burden.

In any case, the committee should watch out that an excise tax does not result in overcharging. In its testimony last summer, Lederle testified that the price of DPT had risen to $11.40 per dose, of which $8.00 went toward a sort of "self-insurance" lawsuit reserve fund.2/ Because the new law provides some protections from liability for Lederle, and because many consumers can be expected to accept the more limited compensation available from the trust fund, Lederle's total liability costs will be reduced. To allow Lederle to pass on the trust fund tax on top of their lawsuit tax permits them to charge consumers twice for the same injured victims. Consumers should not have to pay for both the trust fund and Lederle's lawsuit fund, when they can recover compensation from only one.

In conclusion, litigation over vaccine-related injuries has already proved to be a risky venture. A couple of plaintiffs have won, some have settled, and others have lost. It is the need to replace this lawsuit lottery with predictability, for both plaintiffs and defendants, that has motivated the search for better alternatives. The compensation program before you is just such an alternative. Please approve the excise tax without allowing the program to be relegislated. Thank you again for the opportunity to testify. I'd be pleased to answer any questions you may have.

1/ HALT is aware that some contend the pertussis vaccine may be more dangerous than the threat that would be posed by whooping cough if the vaccine was not required. See, e.g., Coulter & Fisher, DPT: A Shot in the Dark (Warner 1985). This controversy lies outside of HALT's expertise and organizational concerns.

2/ See, "Statement On Vaccine Injury Compensation," by Robert Johnson, President, Lederle Laboratories Division, American Cyanamid Company, Before the Subcomm. on Health and Env't, at 2 (July 25, 1986).

Chairman RANGEL. Thank you very much for sharing your views with us.

Our next witness is Ms. Marge Grant, president of Determined Parents to Stop Hurting Our Tots.

STATEMENT OF MARGE GRANT, PRESIDENT, DETERMINED PARENTS TO STOP HURTING OUR TOTS, BEAVER DAM, WI

Mrs. GRANT. I am Marge Grant, and I am pleased to honor your invitation to testify at this hearing on behalf of Wisconsin's DPT-SHOT organization of which I am president.

I appreciate the opportunity to present for the printed record this 5-minute prepared statement and would like to submit additional material for the record by March 20.

The members of the organization which I have come here to represent are comprised of Determined Parents To Stop Hurting Our Tots, some of whom have children who have died or suffered vaccine damage. Our concerns are mainly of an educational/supportive nature, in assisting other parents to become better informed about the vaccines that are administered to our children, in the hope we can avoid any more devastating injuries such as our son Scott suffered from DPT vaccine 26 years ago.

Scott's severe injuries are permanent. He suffers from spastic-quadriplegia. He is nonambulatory and mentally retarded. His profound disabilities require 24-hour-a-day care which has been provided all his life in our home by my husband, Jim, and himself. I mention Scott's incapacitated condition only to give you an idea of the costly care he has required all of his life and shall continue to need.

Needless to say, we had hoped that the authors of the compensation bill would have seen fit to include persons like Scott to qualify for the $250,000 recovery award but, unfortunately, it did not happen. I wonder how many other parents of DPT victims are as shocked and as disappointed as we are to learn after Congress passed this discriminatory bill that their maimed and crippled children who suffer profoundly day and day and year after year, indeed, a lifetime, were not given equal consideration and, indeed, excluded from this aspect of the vaccine injury compensation program.

Considering the many flaws and serious deficiencies in this piece of legislation, it is clear it would not have passed the Congress on its own merits. It is indeed obvious why it was nothing short of pushed through on the last day at the 11½ and a half hour of the 99th Congress by a voice vote only late at night.

One month later, on November 14, 1986, President Reagan signed this highly controversial bill despite what he described as doing so with serious reservations about the provisions which create the no-fault compensation for vaccine injured children.

The President is quoted further as saying, "Any acceptable measure to implement a vaccine compensation program should structure the program so that no funding will be provided from the Treasury of the United States."

In other words, the President has advised that tax dollars must not be used to fund the program.

I wholeheartedly agree with the President and will once again repeat our firm convictions from day one on this crucial issue, and that is we must not allow abuse of the taxing power of the Government to take money from the innocent to compensate the guilty.

The vaccine industry and vaccine administrator have known for 50 years that the impure pertussis vaccine was maiming and killing children but chose not to clean up their act, nor the vaccine.

In my judgment, they must now pay the penalty out of their pockets and not the taxpayers'.

This conspired concealment was imposed upon the American public until 5 years ago when NBC's documentary, "DPT: Vaccine Roulette" finally brought about awareness by shedding light on the tragic matter.

In closing, I want to share with this committee a most interesting development that is well on its way in Wisconsin. That is, more and more physicians are refusing to immunize patients in their offices. Instead they are advising parents to take their children to the public clinics to receive innoculations.

When the doctors were asked why they were doing this, the answer was to avoid liability.

In this context then, should all physicians choose to follow this same route, and they may very well, it would burden the taxpayer to supply the additional vaccines that would be needed in the public clinics. Thus any surcharge or any excise tax which I have heard repeatedly here this morning, I think, would be a very bad way indeed because it would still come out of the taxpayers' pockets.

In light of the many, many flaws contained in this legislation, some of which I have outlined above, I strongly oppose the funding of the childhood no-fault vaccine injury compensation program.

I would be happy to answer any questions you might have.

[The prepared statement follows:]

D etermined
P arents
T o
S top
H urting
O ur
T ots

March 19, 1987

Joseph K. Dowley, Chief Counsel
Committee on Ways and Means
1102 Longworth House Office Building
Washington, D.C. 20515

Dear Mr. Dowley:

I am returning for the printed record of the March 5, 1987 hearing on the funding of the Childhood Vaccine Injury Program, my corrected testimony.

Also for the printed record I've enclosed my originally prepared statement with a "postscript" added. Both pages are now on legal size paper and in compliance pursuant to instructions given me.

In response to my oral testimony and remarks to Mrs. Kennely, that there have been fabricated whooping cough outbreaks, I respectfully submit for the printed record, an anlysis for the states of Wisconsin and Maryland, for the year 1982 of "reported" cases of Bordetella pertussis infection.

The Maryland one has been published in the January 1983 Maryland State Medical Journal. The one for Wisconsin was presented at the April 26, 1983 meeting of the Interagency Group To Monitor Vaccine Development, Production and Usage, in Rockville, Maryland. Both analyses were professionally done by leading scientists of The Bell Of Atri, Inc.

Interestingly, the Wisconsin and Maryland so-called outbreaks, sprung up over night after NBC's documentary "DPT: Vaccine Roulette" shocked viewers across the nation and obviously hit some raw nerves. And with this exposure of the injurious effects of the unimproved 50 year old crude and toxic pertussis vaccine has on humans, the only defense is to call for its continued use, lest we have a resurgence of pertussis infection ... even if the outbreaks are fabricated. Please do not hesitate if you have any questions, as I have volumes of information on "reported" cases of pertussis in Wisconsin, but do not want to exceed the 10 page limit, for this hearing record.

Sincerely,
Marge Grant
Mrs. Marge Grant

© 1984 M. Grant

SCOTTIE GRANT

YOUR CHILD MAY BE NEXT !

Phone: (414) 887-1133
Jim & Marge Grant
P.O. Box 543
Beaver Dam, WI 53916

D etermined
P arents
T o
S top
H urting
O ur
T ots

Testimony by: Mrs. Marge Grant
Mother of Scottie Grant, who is a
DPT - VACCINE - VICTIM

March 5, 1987

Honorable Charles Rangel, Chairman
House Subcommittee On Select Revenue Measures
1100 Longworth Building
Washington, D.C. 20515

9:30 A.M. Hearing On The Funding Of The Childhood Vaccine Program

Mr. Chairman And Subcommittee Members:

I am Marge Grant and am pleased to honor your invitation to testify at this hearing, on behalf of Wisconsin's DPT-SHOT organization of which I am President.

I appreciate the opportunity to present for the printed record this five minute prepared statement and would like to submit additional material for the record by March 20.

The members of the organization which I've come here to represent are comprised of "Determined Parents To Stop Hurting Our Tots," some of whom have children who have died or suffered vaccine damage. Our concerns are mainly of an educational/supportive nature, in assisting other parents to become better informed about the vaccines that are administered to our children, in the hope we can avoid any more devastating injuries such as our son Scott suffered from DPT vaccine 26 years ago.

Scott's severe injuries are permanent. He suffers from spastic-quadriplegia. He is non-ambulatory and mentally retarded. His profound disabilities require total 24 hour care, which has been provided all of his life in our home by my husband Jim and myself. I mention Scott's incapacitated condition only to give you an idea of the costly care he has required all of his life and shall continue to need.

Needless to say, we had hoped the authors of the compensation bill, would have seen fit to include persons like Scott to qualify for the $250,000 recovery awards, but it unfortunately did not happen. And I wonder how many other parents of DPT victims were as shocked and disappointed as we were, to learn "after" Congress passed this "discriminatory" bill, that their maimed and crippled children who suffer profoundly day after day, year after year, indeed a lifetime .... were not given equal consideration, and indeed excluded from this aspect of the vaccine-injury compensation program.

Considering the many flaws and serious deficiencies in this piece of legislation, it is clear, it would not have passed Congress on its own merits. And it is indeed obvious why it was nothing short of "pushed through" on the last day, at the eleventh and a half hour of the 99th. Congress, by voice-vote only ... late at night.

One month later, on November 14, 1986, President Reagan signed this highly controversial bill, despite what he described as doing so with "serious reservations" about the provisions which create the no-fault compensation program for vaccine-injured children.

(CONTINUED)

SCOTTIE GRANT

© 1984 M. Grant

YOUR CHILD MAY BE NEXT !

PHONE: (414) 887-1133

Jim & Marge Grant
P.O. Box 543
Beaver Dam, WI 53916

The President is further quoted as saying: "Any acceptable measure to implement a vaccine compensation program should structure the program so that no funding will be provided from the treasury of the United States."

In other words, the President has advised that "tax-dollars" must not be used to fund the program.

I wholeheartedly agree with President Reagan and will once again repeat our firm convictions, from day one, on this crucial issue. That is: we must not allow abuse of the taxing-power of the Government, to take money from the innocent, to compensate the guilty.

The vaccine industry and vaccine administrators have known for fifty years that the impure pertussis vaccine was maiming and killing children, but chose not to clean up their act ... nor the vaccine.

In my judgment, they must now pay the penalty, and out of their pockets, not the taxpayers'.

This conspired concealment was imposed upon the American public until five years ago when NBC's documentary, "DPT: VACCINE ROULETTE" finally brought about awareness by shedding light on this tragic matter.

In closing, I want to share with this Committee a most interesting development that is well on its way in Wisconsin. That is, that more and more physicians are refusing to immunize patients in their offices. Instead, they are advising parents to take their children to the public clinics to receive inoculations.

When the doctors were asked why they were doing this, the answer was, to avoid liability.

In this context then, should all physicians choose to follow this same route, it would burden further the taxpayer to supply the additional vaccines that would be needed in the public clinics. Thus, any surcharge or excise tax placed on vaccines as has been earlier suggested may be a way to finance the compensation fund, will be paid for with tax-dollars.

In light of the many many flaws contained in this legislation, some of which I have outlined above, I strongly oppose the funding of the Childhood No-Fault Vaccine-Injury Compensation Program.

I will be happy to answer any questions you may have.

P.S. I would like to reemphasize that this Committee holds the key as to whether or not American children will have imposed upon them the tragically flawed compensation law within (P.L. 99-660) that was put together and spirited through the 99th Congress by the collaborative efforts of the American Academy of Pediatrics, the Governing Board of the Virginia-based Dissatisfied Parents, and a handful of Congressmen. It is the judgement of "Determined Parents To Stop Hurting Our Tots" that the select few just mentioned, have chosen to play God with the health, welfare, and indeed the life of our innocent children. Sadly, this compensation proposal is portrayed as the Savior of America's children, when in fact the exact opposite is true. Mr. Rangel and Subcommittee Members: Please do not be fooled by this Trojan horse. It invites abuse and fraud.

I would like to repeat what I told Senator Hawkins and her Subcommittee at the very first hearing on this matter, on May 7, 1982:

> "WHEN IT HAPPENS TO YOUR OWN CHILD, THERE ARE 'NO BENEFITS' AND THE RISKS ARE 100 PERCENT!
>
> REMEMBER, THERE ARE NO SPECIAL NAMES ON THE VIALS OF 'FAULTY VACCINES'. THE NEXT VICTIM COULD BE YOURS!"

We pray that this Committee will allow good morals to dictate, not special interests or political motives. For the sake of your children, grandchildren, indeed your neighbors' children, please do not create a funding mechanism that would enable enactment of this anti-consumer law.

The Open Forum

To the Editor:

The editorial by Heldrich (*Journal*, October 1982, p. 25) offers epidemiologic evidence "that [currently employed] pertussis immunization [procedures] confers an immunity of 94 percent," lists some of the minor and major adverse clinical reactions that follow pertussis vaccine administration and suggests as a desirable goal "development of a safer vaccine; one that does not produce complications but effectively immunizes." In this regard, our recent observations might be of interest to *Journal* readers.

In early September, the Immunization Program Coordinator, State of Maryland Department of Health and Mental Hygiene, made available to us for independent analysis the computer print-out of information accumulated up to 31 August on the "Pertussis Outbreak, Maryland 1982," an outbreak, reportedly, involving 40 children and a young adult.

Examination of the computerized information for match of patient age with DPT vaccine administration number permitted separation of the 41 reported cases of whooping cough into two groups. One group consisted of 15 children: those too young to receive the first DPT vaccine injection (age 1 month) and those who might have received the first vaccine injection so recently there might not have been sufficient time-lapse for a protective antibody response (age 2 months). The other group was made up of 25 children (age 3 months to 12 years) and a young adult (age 23 years).

In the latter group of 26 reported cases of whooping cough, 20 cases occurred in individuals who had received at least one injection of DPT vaccine. Of these 20 reported cases, 7 occurred in individuals over 12 months of age (age 20 months to 23 years). Six of the 7 individuals had received 1 or more DPT vaccine injections; of these 6, 3 received 4 vaccine injections; 1, 3 injections and 1, 5 injections. The remaining case received no DPT vaccine and for this case, there is no evidence in the computerized data to suggest this 5-year-old child presented clinical signs or symptoms, serologic or bacteriologic findings of *Bordetella pertussis* infection. Only for a single case was there substantial evidence in the computerized data to suggest a case of *B. pertussis*-induced whooping cough. This case had a whooping cough, a positive fluorescent antibody test, and a positive bacteriologic culture.

If one assumes (which we do not) that each of the 7 cases represents a case of whooping cough caused by *B. pertussis*, then the findings are disquieting and raise a serious question about vaccine efficacy. Five of the 7 children had received 3 or more DPT vaccine injections.

Next, interest was centered on the clinical, serologic, and bacteriologic recordings for 34 cases of whooping cough reported for children 1 to 10 months of age.

Only 2 of the 15 children reported to have experienced a whooping cough yielded substantial evidence that their whooping cough might have been caused by *B. pertussis*: both these children gave positive findings in *B. pertussis* antibody and culture tests. Another gave less substantial evidence for a *B. pertussis*-caused whooping cough: this child gave a negative finding in the antibody test, but a positive finding in the culture test.

Eighteen of the 34 children are reported not to have experienced a whooping cough [information on this point was not known for another]. Of these 18, 12 are reported not to have shown any of the other 4 designated clinical signs (pneumonia, apnea, seizure, encephalitis).

Another 5 of the 12 children might be included in the same category (no evidence in the computerized print-out to show that the children had *B. pertussis*-induced whooping cough) since tests selected to demonstrate this were either negative, not done, or the results are pending.

Of the remaining 7 there is substantial evidence (positive results in both antibody and culture tests) that only 1 might have experienced *B. pertussis* infection, and if this infection occurred, it occurred in this 2-month-old child without producing clinical signs and symptoms of disease. In the other 6 cases the results in antibody and culture tests were variable or were not done, and the reported results cannot, justifiably, be used to suggest a presumptive, and certainly not a definitive, diagnosis of *B. pertussis*-induced whooping cough.

Of the 18 children reported to have had the disease whooping cough, but not to have exhibited the clinical sign of a whooping cough, 6 are reported to have 1 or more than 1 of the other specified clinical signs (pneumonia, apnea, seizures, encephalitis), but for only 1 is there substantial evidence (positive results in both *B. pertussis* antibody and culture tests) that the exhibited clinical sign (apnea) might have been induced by *B. pertussis* infection. If this is so, then the infection occurred in this 2-month-old child following vaccination with DPT vaccine by the recommended scheduling procedure. There is no substantial evidence that any of the other 5 children in this group of 6 was infected with *B. pertussis* (results of serologic and bacteriologic tests variable or not done).

This analysis shows: (1) that for the 41 cases included in the computer print-out concerned with the "Pertussis Outbreak, Maryland 1982," for only 5 cases is there sufficient evidence for a presumptive diagnosis of *B. pertussis*-induced whooping cough. These cases occurred in children at age 2 months (2 children), 3 months, 10 months and 4 years. The children had been injected with DPT vaccine the following number of times: 1, 1, 1, 2, 4, respectively. Except possibly for the 10-month-old child, each child received DPT vaccine according to the recommended schedule. This finding, together with findings given in earlier paragraphs in this letter raises serious questions about the efficacy of the DPT vaccine administered to the children who were the cases in the computerized print-out sent to us for analysis; (2) that the criteria used for even a presumptive diagnosis of *B. pertussis*-induced whooping cough in the computerized print-out "Pertussis Outbreak, Maryland, 1982" are seriously unsatisfactory and have led to seriously flawed conclusions (News Release, State Department of Health and Mental Hygiene, 31 August 1982: "Maryland Whooping Cough Epidemic Now Numbers 41 Infants and Youths").

It seems to us that the findings in this analysis emphasize the importance of the prompt realization of the desirable goal suggested in the Heldrich editorial: "the development of a safer vaccine; one that does not produce complications but effectively immunizes. Such a vaccine remains in the future, but the impetus supplied by present public concern and legislative pressure may stimulate its development."

J. ANTHONY MORRIS PhD
JOHN C. HOFFMAN MS
Bell of Atri, Inc.

The tabular material on which information in this letter is based will be sent to those who request it. Send requests to Dr. J. Anthony Morris, Vice-Chairman, Bell of Atri, Inc., P.O. Box 40, College Park, MD 20740.

[The Bell of Atri, Inc., is a public interest organization concerned with health, science, and public policy. AW]

●

★(underscoring by Marge Grant)

AN ANALYSIS
of
REPORTED PERTUSSIS CASES IN WISCONSIN IN 1982

by

J. Anthony Morris, Ph.D.

and

John Chriss Hoffman, M.Sc.

The Bell of Atri, Inc.
(A Public Interest Organization Concerned with
Health, Science and Public Policy)
College Park, Maryland

Presented at a meeting of the Interagency Group to Monitor Vaccine Development, Production, and Usage, in response to a "request [for] information from interested parties to assist in preparation of a report on pertussis and pertussis vaccines" (Federal Register, 8 April 1983)

Rockville, Maryland
26 April 1983

The Federal Register notice for this meeting lists for discussion here and for incorporation into a written report the following item: "Diagnosis, reporting, and recordkeeping of incidence and severity of pertussis and adverse reactions to pertussis vaccines."

My comments will be concerned with one aspect of that listed item: recordkeeping on the incidence of pertussis.

I will discuss records on "Reported Pertussis Cases, 1982," in Wisconsin and I will submit for consideration for inclusion as an addendum to the written report, our published analysis of the records on "Pertussis Outbreak, 1982," for Maryland.

I will now discuss the information in TABLE I in the handout.

Let's assume for the purpose of discussion of the data in TABLE I that each of the 43 reported pertussis cases in Wisconsin in 1982 represents a patient with Bordetella pertussis infection.

There are listed 16 children less than 1-month through 2-months of age. These children were either too young to be vaccinated or, if vaccinated, they might not have had sufficient time to respond with formation of protective antibody before their infections occurred.

Next, there are listed 25 children 3 to 36 months of age, a teenager at 14 years and a young adult at 23 years. Of these 27 individuals, vaccination history was not known for 9. Of the 18 individuals with recorded vaccination histories, only 2 (number 22, a 4-month-old and number 42, a 6-month-old) had histories of not being vaccinated.

The remaining 16 cases had received 1, 2, 3, 4 or 6 vaccine injections. The interval in days between the most recent vaccine injection and cough onset ranged from minus 9 days (number 24) to 90 days (number 27): both cases were in the 5-month age group.

These findings mean that, except for cases 22 and A2, who had not been vaccinated, and possibly case 41, who had received only 2 vaccine injections in 12 months, none of the reported cases in Wisconsin in the age group 3-months to 23-years, for whom vaccine histories were recorded, can be attributed to failure to administer vaccine according to one or the other of the recommended vaccination schedules.

In addition, these findings mean that serious questions arise concerning the efficacy of the pertussis vaccine lots used to vaccinate the listed individuals.

I will now discuss the information in TABLE II in the handout.

Of the 5 listed signs and symptoms (cough, whoop, apnea, seizure and encephalitis), one was common for all reported cases (except for case 8, where "unknown" was recorded): this common sign was cough.

For bacteriologic cultures, we assume that a positive culture represents confirmation of Bordetella pertussis infection. Sixteen cases yielded B. pertussis on culture. Seven (in the order listed - 28, 14, 26, 22, 21, 41, 4) of the 16 positive-culture cases showed a single illness sign: this sign was a cough--not a whoop, but a cough. Seven (2, 24, 25, 43, 42, 32, 33) of the other positive-culture cases had a whooping cough and 2 (38, 23) had breathing difficulty.

An interpretation of the significance of these findings will be given in a few minutes.

In FA (fluorescent antibody) tests, all but 2 of 33 cases examined, yielded positive results (negative cases were 25 and 42). The high frequency of positive FA findings in this tabulation raised a question about the significance of presence of this antibody.

It is generally accepted that a demonstration of fluorescent antibody by itself, in the absence of an antibody demonstrated by another technique, is of limited value. As recently as December 1982, Granström reported that "Laboratory verification of whooping cough, which is almost exclusively based on isolation of Bordetella pertussis, [has led to] attempts . . . to develop serologic assays, but none has been found to be quite satisfactory" (The Journal of Infectious Diseases, 146: 741-745, December 1982).

Nevertheless, we wanted to know how the FDA interpreted the presence of this antibody. Accordingly, we asked the FDA the following question: What does presence of this [FA] antibody mean?

The FDA 3 February written response was the following: ". . . some workers do not consider previously developed serologic assays, such as the immunofluorescence assay . . . to be totally satisfactory to serve as a laboratory verification of [pertussis] infection" (underscoring mine).

While the FDA response might not be completely satisfactory, it is, at least, suggestive. They do respond by saying that "some workers do not consider" the FA test "to be totally satisfactory . . . as a . . . verification of [pertussis] infection."

I will comment later on the FA findings.

Of the 43 reported Wisconsin cases, 10 (16, 20, 31, 39, 9, 40, 10, 19, 5, 37) showed a single sign of illness--a cough. Another reported case (case 8 in the 5-months-old group) is of particular interest: all information on this reported case, except for age, is recorded as unknown.

Five (6, 36, 7, 17, 27) reported cases with cough had a whooping cough, but a negative or unknown bacteriologic culture. As far as we can determine, no effort was made to demonstrate the cause of the whooping cough. It is known that a whooping cough can be caused by viruses and by bacteria other than B. pertussis.

What does the information in TABLE II mean?

It means that 10 (16, 20, 31, 39, 9, 40, 10, 19, 5, 37) of the 43 reported pertussis cases had nothing more than a cold and a positive result in an essentially meaningless serologic test. No information in the records justifies listing these 10 as pertussis cases

It means that 12 (1, 29, 3, 6, 13, 35, 36, 7, 12, 34, 17, 27) of the 19 with a whooping cough with a negative or unknown bacteriologic culture, might be listed as a suspected pertussis case, but cannot justifiably be listed in a way to imply that these cases are definitively diagnosed pertussis cases. This is especially so, in the absence of even minimum effort to rule out the possibility that these 12 cases were non-Bordetella induced whooping cough. This equally applies to 4 (11, 15, 30, 18) cases without a whooping cough, but with breathing difficulty.

It means that one case (8); for whom there was no information recorded except age; cannot, on the basis of the record, be listed as a pertussis case.

Remaining are 16 cases--those cases that yielded B. pertussis on culture--for whom there is information in the record that justifies listing these cases as B. pertussis induced whooping cough. Wisconsin reported 43 pertussis cases.

(added underscores above by Marge Grant)

The information given in this comment on recordkeeping on the incidence of pertussis in Wisconsin in 1982 and in our published account on recordkeeping on the incidence of pertussis in Maryland in 1982 provides for me a new basis for reading the neatly arranged numbers in the Centers for Disease Control Morbidity and Mortality Weekly Report, "summary of cases of specified notifiable diseases." When I read the numbers for pertussis in Wisconsin and in Maryland, I now read these as fiction and I wonder if all of those other numbers for other diseases in other states fall into the same category.

TABLE I

Patient age, vaccine administration number and interval between last vaccine dose and cough onset in all 43 reported pertussis cases in Wisconsin in 1982

Age (mos)	Case	DPT vaccine administrations (number of times)	Date		Interval between last dose and cough onset
			Last vaccine dose	Cough onset	
<1	16	0			
1	1	0			
	11	0			
	15	0			
	20	0			
	28	0			
	29	0			
	30	0			
	38	0			
2	2	0			
	3	0			
	6	1	6/12/81	1/17/82	7 mos
	13	0			
	14	1	3/11/82	3/12/82	1 day
	31	0			
	35	1	8/10/82	8/27/82	17 days
3	26	1	5/27/82	6/18/82	22 days
	36	1	8/13/82	9/ 4/82	22 days
	39	1	8/ 2/82	9/15/82	44 days
4	7	?			
	9	2	1/ 5/82	2/21/82	47 days
	12	1	2/ 2/82	3/ 6/82	32 days
	22	0			
	23	?			
	34	?			
5	8	?			
	17	1	7/21/82	7/21/82	0 days
	21	2	2/ 3/82	3/15/82	42 days
	24	2	6/25/82	6/16/82	-9 days
	27	1	4/27/82	7/13/82	3 mos
	40	2	10/ 1/82	10/ 7/82	6 days
6	25	2	6/21/81	1/17/82	7 mos
	42	0			
7	10	3	11/20/81	1/27/82	2 mos
8	0	-			
9	19	3	2/22/82	3/ 6/82	12 days
10	43	?			
11	0	-			
12	41	2	2/ 2/82	3/ 6/82	32 days
20	5	?			
24	18	?			
	32	4	3/ /81	7/18/82	15 mos
36	37	?			
14(yrs)	33	6	6/ 8/78	5/30/82	4 yrs
23(yrs)	4	?			

TABLE II

Reported pertussis cases in Wisconsin in 1982: Clinical and laboratory findings in children <1 to 36 months of age, in a teenager and in a young adult

Age (mos)	Case	Findings						
		Clinical*					Serologic (FA)	Bacteriologic (culture)
		C	W	A	S	E		
<1	16	Y	N	N	N	U	+	U
1	1	Y	Y	Y	N	N	+	-
	11	Y	N	Y	Y	N	U	-
	15	Y	N	Y	N	U	+	U
	20	Y	N	N	N	N	+	-
	28	Y	N	N	N	N	+	+
	29	Y	Y	Y	Y	U	+	U
	30	Y	U	Y	N	U	+	U
	38	Y	N	Y	N	N	U	+
2	2	Y	Y	N	N	N	+	+
	3	Y	Y	Y	N	N	+	-
	6	Y	Y	N	N	N	ND	U
	13	Y	Y	Y	N	U	U	U
	14	Y	N	N	N	N	+	+
	31	Y	U	N	N	N	+	-
	35	Y	Y	Y	N	N	+	-
3	26	Y	N	U	N	N	+	+
	36	Y	Y	N	N	N	+	-
	39	Y	N	N	N	N	+	U
4	7	Y	Y	N	N	N	+	-
	9	Y	U	N	N	N	+	-
	12	Y	Y	Y	N	U	U	U
	22	Y	N	N	N	N	+	+
	23	Y	N	Y	N	N	+	+
	34	Y	Y	Y	N	N	+	U
5	8	U	U	U	U	U	U	U
	17	Y	Y	U	N	U	U	U
	21	Y	N	U	N	N	+	+
	24	Y	Y	N	N	N	+	+
	27	Y	Y	N	N	N	+	-
	40	Y	N	N	N	N	ND	ND
6	25	Y	Y	U	N	N	-	+
	42	Y	Y	N	N	N	-	+
7	10	Y	N	N	N	N	+	-
9	19	Y	U	U	U	U	+	ND
10	43	Y	Y	N	N	N	+	+
12	41	Y	N	N	N	N	+	+
20	5	Y	U	U	U	U	+	U
24	18	Y	U	Y	N	N	+	ND
	32	Y	Y	N	N	N	+	+
36	37	Y	U	U	U	U	+	U
14(yrs)	33	Y	Y	N	N	N	U	+
23(yrs)	4	Y	N	N	N	N	U	+
Positives in 43 reported cases		43	19	13	2	0	31	16

*C = cough; W = whoop; A = apnea; S = seizure; E = encephalitis.

Y = yes; N = no; U = unknown; ND = not done.

Chairman RANGEL. Thank you. We appreciate your testimony. Mr. Coyne.

Mr. COYNE. I have no questions.

Chairman RANGEL. Mrs. Kennelly.

Mrs. KENNELLY. I got lost somewhere, Mrs. Grant. What are you proposing as the funding mechanism?

Mrs. GRANT. I don't believe this entire bill should go into law. I think there are so many flaws. I guess my first real objection is it will, indeed, bail out those very persons who have hurt our children. The manufacturers knew about this. They could have changed it. They didn't; they chose not to. They are now asking you to bail them out, and that is not fair. That is not fair.

As Dr. Morris said, to compensate a child who is hurt is not the answer. The answer is clean up the vaccine. Let's put some funding into that and see to it that it is done.

I don't think this bill should be enacted at all.

Mrs. KENNELLY. Mrs. Grant, what happens to the children in the interim between the clean-up and today?

Mrs. GRANT. I am glad you asked that. It is at least 12 years ago that I went public on this issue. At that time, I said put a moratorium on the pertussis part. That is the major culprit as far as I am concerned.

Mrs. KENNELLY. Say that again.

Mrs. GRANT. Put a moratorium on the use of the current pertussis vaccine. Of course, they will cry we will then have epidemics. They are fabricating epidemics. I shall provide data to substantiate fabrication and that there no longer are pertussis epidemics.

Mrs. KENNELLY. Because we have vaccines.

Mrs. GRANT. That is a good argument and maybe that is true, but I am inclined to think there are other aspects that might have contributed to the fact that there are less. There is hardly any pertussis around. I just don't agree on that.

Mrs. KENNELLY. This is why we have hearings. That is the whole point of hearings so we can hear disagreeing points of view. Obviously, this hearing this morning highlights that the disagreement is not only in the funding mechanism but the disagreement is on the whole approach to the question. This even makes it more difficult.

Mr. Chairman, could I just ask Ms. Chalfie something?

You said something about the media caught all our attention. You supported the excise taxes, but you said you didn't want that passed on to the consumer. That is almost an impossibility.

Ms. CHALFIE. I thought that might be the case. That is why I said I would just like the committee to be sensitive to the possibility of overcharging, that we should not pay for both the compensation fund and the liability reserve fund.

Mrs. KENNELLY. If you had to choose between one or the other, which would be your druthers?

Ms. CHALFIE. Do you mean which should consumers pay for? The compensation fund—the liability fund should not be subsidized by consumers.

Mrs. KENNELLY. Did you want to say something, Mrs. Grant?

Mrs. GRANT. I know this is not going to be accepted, of course, but I can tell you another way that we could reconcile some of the

problems, and that is remove the mandate. We have heard mandated vaccines all over this room this morning. As far as I am concerned, that is unconstitutional. I don't think anything should be pushed on to these children.

In Wisconsin in 1981, a law went into effect, which changed the law. In Wisconsin we now have the right to choose whether or not we want any vaccines, and we don't have to take any if we don't so choose. I know this is not accepted very well, but I know that is the alternative.

Mrs. KENNELLY. Mrs. Grant, if I were you, I would feel exactly the same way. You don't have to apologize. I am pleased that with your feelings you took the time to come and talk to us.

Mrs. GRANT. I appreciate that.

Mrs. KENNELLY. Thank you.

Thank you, Mr. Chairman.

Chairman. RANGEL. Let me thank the panel for sharing a different view on this. I would remind you it is not, our mandate to get involved in the substantive question. However we should fund it or not probably relates more to your testimony than whether there should be a bill or not, so we really appreciate the input that you have had. Have a safe trip back home.

Mrs. GRANT. Thank you very much. I appreciate that.

[Whereupon, at 12 noon, the hearing was adjourned.]

○